MTN-003 Training

Completion of the revised

MTN-003 Unused Product Returns Slip – Version 2

& the new

Product Returns CRF

Things to Consider

MTN-003 Unused Product Returns Slip – Version 2

MTN-003 Unused Product Returns Slip – Version 2

- **Completed by site pharmacists**
  - **At every monthly study visit through the Product Use End Visit (PUEV)**
  - **At interim visits when:**
    - **product is returned to the pharmacy due to product hold/discontinuation – or -**
    - **product is re-supplied/re-issued, even if no product is returned at the interim visit.**
      - If product is not returned to the pharmacy (i.e., no hold/discontinuation at the interim visit), AND if product is not re-supplied, or re-issued at an interim visit, then the slip should **not** be completed for that interim visit.

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MTN-003 Unused Product Returns Slip

- Serves as source documentation for the new Product Returns CRF
- Two-part, no carbon required (NCR) form – version 2 is A4 size
  - Original (top part) is white, labeled "Pharmacy" at bottom of page
  - copy (bottom part) is yellow and labeled "Clinic" at bottom of page
- Once completed, yellow (copy) goes to site clinic. White (original) is filed in participant's study pharmacy records.

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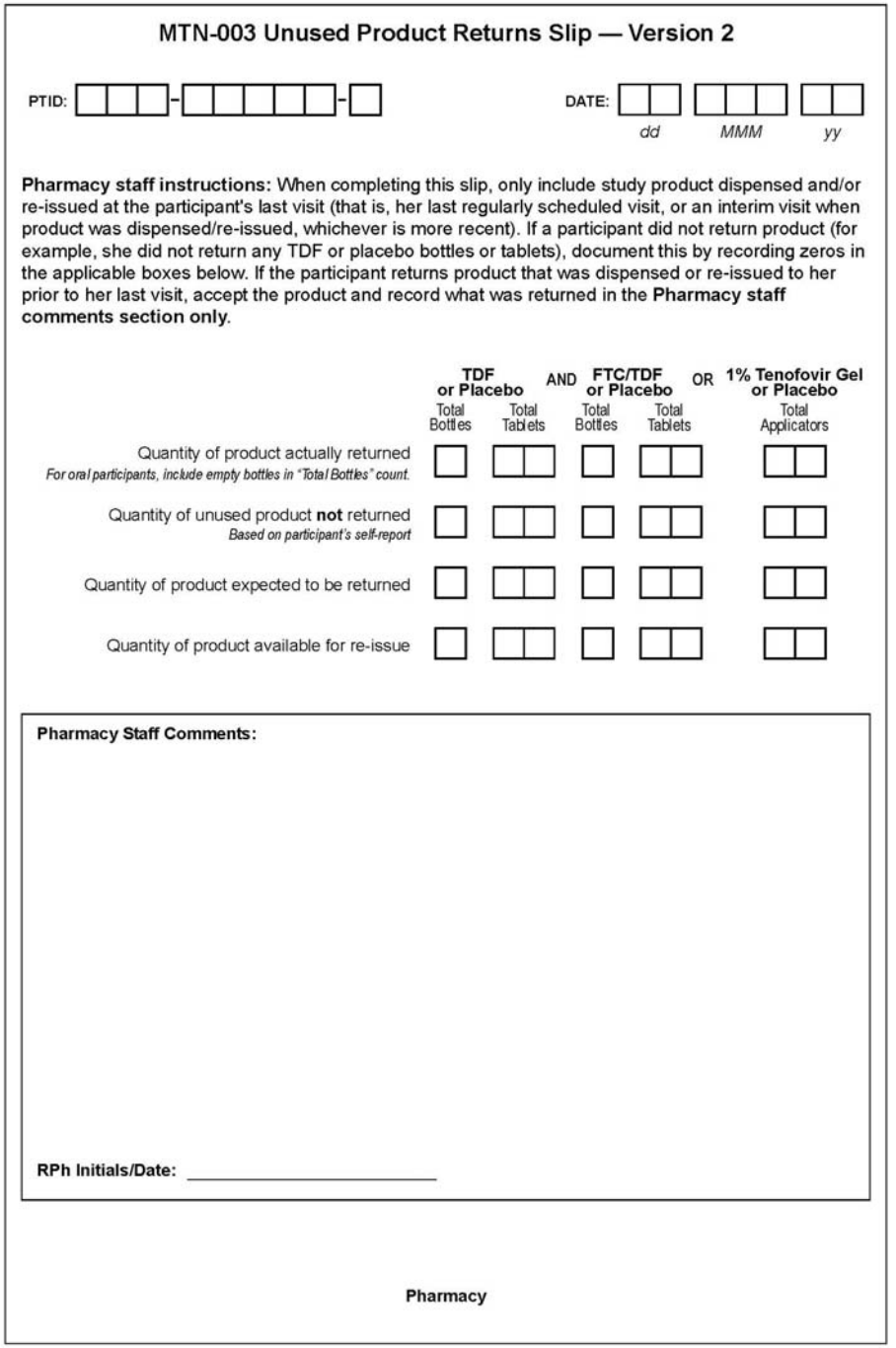
MTN-003 Unused Product Returns Slip – Version 2



MTN-003 Unused Product Returns Slip — Version 2

PTID: ☐☐☐-☐☐☐☐☐-☐ DATE: ☐☐ (dd) ☐☐☐ (MMM) ☐☐ (yy)

Pharmacy staff instructions: When completing this slip, only include study product dispensed and/or re-issued at the participant's last visit (that is, her last regularly scheduled visit, or an interim visit when product was dispensed/re-issued, whichever is more recent). If a participant did not return product (for example, she did not return any TDF or placebo bottles or tablets), document this by recording zeros in the applicable boxes below. If the participant returns product that was dispensed or re-issued to her prior to her last visit, accept the product and record what was returned in the **Pharmacy staff comments section only.**

	TDF or Placebo		AND **FTC/TDF or Placebo**		OR **1% Tenofovir Gel or Placebo**
	Total Bottles	Total Tablets	Total Bottles	Total Tablets	Total Applicators
Quantity of product actually returned *For oral participants, include empty bottles in "Total Bottles" count.*	☐	☐☐	☐	☐☐	☐☐
Quantity of unused product **not** returned *Based on participant's self-report*	☐	☐☐	☐	☐☐	☐☐
Quantity of product expected to be returned	☐	☐☐	☐	☐☐	☐☐
Quantity of product available for re-issue	☐	☐☐	☐	☐☐	☐☐

Pharmacy Staff Comments:

RPh Initials/Date: _____

Pharmacy

MTN-003 Unused Product Returns Slip – Version 2

Let's take a closer look…

MTN-003 Unused Product Returns Slip — Version 2

PTID: ☐☐☐-☐☐☐☐☐-☐ DATE: ☐☐ ☐☐☐ ☐☐
dd *MMM* *yy*

OR RETURNED

Pharmacy staff instructions: When completing this slip, only include study product dispensed and/or re-issued at the participant's last visit (that is, her last regularly scheduled visit, or an interim visit when product was dispensed/re-issued, whichever is more recent). If a participant did not return product (for example, she did not return any TDF or placebo bottles or tablets), document this by recording zeros in the applicable boxes below. If the participant returns product that was dispensed or re-issued to her prior to her last visit, accept the product and record what was returned in the **Pharmacy staff comments section only**.

IMPORTANT NOTE

For purposes of completing the slip, the last visit is defined as:

- the last regularly scheduled visit that the participant completed, or
- the last interim visit she completed in which product was returned (i.e., due to product hold/discontinuation) OR re-supplied OR re-issued,

whichever visit (regular or interim) is more recent.

EXAMPLE 1: A participant completes her Month 3 Visit. A week later, her labs come back and she is placed on a product hold. She returns to the site the same day as the hold for an interim visit. She returns all unused study product to the site pharmacist and undergoes a repeat blood draw. The site pharmacist completes the slip at the interim visit to document the product return. For purposes of completing the slip, the last visit is defined as the Month 3 Visit.

The participant returns to the site 3 weeks later for her Month 4 Visit. The hold is still continuing. Site clinic staff notify the site pharmacist that the participant has returned for the visit, and request a completed slip. The site pharmacist completes the slip at the Month 4 Visit, even though no unused product is returned (or in the participant's possession), since completion of the slip is required at each monthly study visit through the PUEV. For purposes of completing the slip, the last visit is defined as the interim visit (since product was returned at the interim visit).

EXAMPLE 2: A participant completes her Month 3 Visit. A week later, her labs come back and she is placed on a product hold. She returns to the site the same day as the hold for an interim visit, and undergoes a repeat blood draw. She does not return any study product. The site pharmacist is notified of the product hold via the MTN-003 Study Product Request Slip, which clinic staff have marked "Hold". The MTN-003 Unused Product Returns Slip is not completed, since no product is returned, re-supplied, or re-issued at this interim visit.

Site staff visit the participant's house 5 days later to retrieve her unused study product. This counts as a second interim visit. The unused product is returned to the site pharmacist, who completes the Unused Product Returns Slip. For purposes of completing the slip, the last visit is defined as the Month 3 Visit. (The interim visit does not count as the last visit, since it did not involve a product return, re-supply, or re-issue).

The participant returns to the site 2 weeks later for her Month 4 Visit. The hold is still continuing. Site clinic staff notify the site pharmacist that the participant has returned for the visit, and request a completed Unused Product Returns Slip. The site pharmacist completes the slip at the Month 4 Visit, even though no unused product is returned (or in the participant's possession), since completion of the slip is required at each monthly study visit through the PUEV. When completing the slip, the last visit is defined as the second interim visit.

EXAMPLE 3: A participant completes her Month 3 Visit. A week later, her labs come back and warrant a repeat blood draw within a week. She returns to the site 5 days later for an interim visit, and undergoes a repeat blood draw. She brings her study product with her, but no product is returned to the pharmacy, as she is not placed on a product hold/discontinuation at this time, and does not need to be re-supplied or re-issued any new product at this time. The MTN-003 Unused Product Returns Slip is not completed, since no product is returned, re-supplied, or re-issued at this interim visit.

Site staff receive the lab results a week later, and all results are normal. They inform the participant by phone and reminder her to return in 2 weeks for her Month 4 Visit.

The participant returns as scheduled for her Month 4 Visit. The site pharmacist completes a slip at the Month 4 Visit. For purposes of completing the slip, the last visit is defined as the Month 3 Visit.

MTN-003 Unused Product Returns Slip – Version 2

Counting and documenting returned study products

MTN-003 Unused Product Returns Slip — Version 2

PTID: ☐☐☐-☐☐☐☐☐-☐ DATE: ☐☐ ☐☐☐ ☐☐
dd *MMM* *yy*

Pharmacy staff instructions: When completing this slip, only include study product dispensed and/or re-issued at the participant's last visit (that is, her last regularly scheduled visit, or an interim visit when product was dispensed/re-issued, whichever is more recent). If a participant did not return product (for example, she did not return any TDF or placebo bottles or tablets), document this by recording zeros in the applicable boxes below. If the participant returns product that was dispensed or re-issued to her prior to her last visit, accept the product and record what was returned in the **Pharmacy staff comments section only**.

Only include returned product from the last visit.

	TDF or Placebo		AND **FTC/TDF or Placebo**		OR **1% Tenofovir Gel or Placebo**
	Total Bottles	Total Tablets	Total Bottles	Total Tablets	Total Applicators
Quantity of product actually returned *For oral participants, include empty bottles in "Total Bottles" count.*	☐	☐☐	☐	☐☐	☐☐
Quantity of unused product **not** returned *Based on participant's self-report*	☐	☐☐	☐	☐☐	☐☐
Quantity of product expected to be returned	☐	☐☐	☐	☐☐	☐☐
Quantity of product available for re-issue	☐	☐☐	☐	☐☐	☐☐

MTN-003 Unused Product Returns Slip — Version 2

PTID: ☐☐☐-☐☐☐☐☐-☐ DATE: ☐☐ ☐☐☐ ☐☐
dd *MMM* *yy*

Pharmacy staff instructions: When completing this slip, only include study product dispensed and/or re-issued at the participant's last visit (that is, her last regularly scheduled visit, or an interim visit when product was dispensed/re-issued, whichever is more recent). If a participant did not return product (for example, she did not return any TDF or placebo bottles or tablets), document this by recording zeros in the applicable boxes below. If the participant returns product that was dispensed or re-issued to her prior to her last visit, accept the product and record what was returned in the **Pharmacy staff comments section only**.

For vaginal participants, count only unused applicators from the last visit that the participant returned.

	TDF or Placebo		AND **FTC/TDF or Placebo**		OR **1% Tenofovir Gel or Placebo**
	Total Bottles	Total Tablets	Total Bottles	Total Tablets	Total Applicators
Quantity of product actually returned *For oral participants, include empty bottles in "Total Bottles" count.*	☐	☐☐	☐	☐☐	☐☐
Quantity of unused product **not** returned *Based on participant's self-report*	☐	☐☐	☐	☐☐	☐☐
Quantity of product expected to be returned	☐	☐☐	☐	☐☐	☐☐
Quantity of product available for re-issue	☐	☐☐	☐	☐☐	☐☐

MTN-003 Unused Product Returns Slip — Version 2

PTID: ☐☐☐-☐☐☐☐☐-☐ DATE: ☐☐ ☐☐☐ ☐☐
dd *MMM* *yy*

Pharmacy staff instructions: When completing this slip, only include study product dispensed and/or re-issued at the participant's last visit (that is, her last regularly scheduled visit, or an interim visit when product was dispensed/re-issued, whichever is more recent). If a participant did not return product (for example, she did not return any TDF or placebo bottles or tablets), document this by recording zeros in the applicable boxes below. If the participant returns product that was dispensed or re-issued to her prior to her last visit, accept the product and record what was returned in the **Pharmacy staff comments section only**.

For oral participants, count the total number of bottles from the last visit that the participant returned, including empty bottles.

	TDF or Placebo		AND	**FTC/TDF or Placebo**		OR	**1% Tenofovir Gel or Placebo**
	Total Bottles	Total Tablets		Total Bottles	Total Tablets		Total Applicators
Quantity of product actually returned *For oral participants, include empty bottles in "Total Bottles" count.*	☐	☐☐		☐	☐☐		☐☐
Quantity of unused product **not** returned *Based on participant's self-report*	☐	☐☐		☐	☐☐		☐☐
Quantity of product expected to be returned	☐	☐☐		☐	☐☐		☐☐
Quantity of product available for re-issue	☐	☐☐		☐	☐☐		☐☐

MTN-003 Unused Product Returns Slip — Version 2

PTID: ☐☐☐-☐☐☐☐☐-☐ DATE: ☐☐ ☐☐☐ ☐☐
dd MMM yy

Pharmacy staff instructions: When completing this slip, only include study product dispensed and/or re-issued at the participant's last visit (that is, her last regularly scheduled visit, or an interim visit when product was dispensed/re-issued, whichever is more recent). If a participant did not return product (for example, she did not return any TDF or placebo bottles or tablets), document this by recording zeros in the applicable boxes below. If the participant returns product that was dispensed or re-issued to her prior to her last visit, accept the product and record what was returned in the **Pharmacy staff comments section only**.

For oral participants, count the total number of tablets from the last visit that the participant returned from all returned bottles combined.

	TDF or Placebo		AND	**FTC/TDF or Placebo**		OR	**1% Tenofovir Gel or Placebo**
	Total Bottles	Total Tablets		Total Bottles	Total Tablets		Total Applicators
Quantity of product actually returned *For oral participants, include empty bottles in "Total Bottles" count.*	☐	☐☐		☐	☐☐		☐☐
Quantity of unused product **not** returned *Based on participant's self-report*	☐	☐☐		☐	☐☐		☐☐
Quantity of product expected to be returned	☐	☐☐		☐	☐☐		☐☐
Quantity of product available for re-issue	☐	☐☐		☐	☐☐		☐☐

For example, at her Month 3 Visit a participant is given the following:

- 1 bottle re-supply of TDF or placebo
- 1 bottle with 2 re-issued tablets of TDF or placebo
- 1 bottle re-supply of FTC/TDF or placebo
- 1 bottle with 2 re-issued tablets of FTC/TDF or placebo.

At her Month 4 Visit, she returns the following:

- 1 bottle containing 4 tablets of TDF or placebo (bottle was re-supplied at Month 3)
- 1 empty bottle of TDF or placebo (bottle was re-issued at Month 3)
- 1 bottle containing 2 tablets of TDF or placebo (bottle was re-supplied at Month 1)
- 1 bottle containing 4 tablets of FTC/TDF or placebo (bottle was re-supplied at Month 3)
- 1 empty bottle of FTC/TDF or placebo (bottle was re-issued at Month 3)
- 1 bottle containing 2 tablets of FTC/TDF or placebo (bottle was re-supplied at Month 1).

At this participant's Month 4Visit, how should the site pharmacist complete the first row of the slip?

	TDF or Placebo		AND	**FTC/TDF or Placebo**		OR	**1% Tenofovir Gel or Placebo**
	Total Bottles	Total Tablets		Total Bottles	Total Tablets		Total Applicators
Quantity of product actually returned *For oral participants, include empty bottles in "Total Bottles" count.*	☐	☐☐		☐	☐☐		☐☐
Quantity of unused product **not** returned *Based on participant's self-report*	☐	☐☐		☐	☐☐		☐☐
Quantity of product expected to be returned	☐	☐☐		☐	☐☐		☐☐
Quantity of product available for re-issue	☐	☐☐		☐	☐☐		☐☐

For example, at her Month 3 Visit a participant is dispensed the following:

- 1 bottle re-supply of TDF or placebo
- 1 bottle with 2 re-issued tablets of TDF or placebo
- 1 bottle re-supply of FTC/TDF or placebo
- 1 bottle with 2 re-issued tablets of FTC/TDF or placebo.

At her Month 4 Visit, she returns the following:

- 1 bottle containing 4 tablets of TDF or placebo (bottle was re-supplied at Month 3)
- 1 empty bottle of TDF or placebo (bottle was re-issued at Month 3)
- 1 bottle containing 2 tablets of TDF or placebo (bottle was re-supplied at Month 1)
- 1 bottle containing 4 tablets of FTC/TDF or placebo (bottle was re-supplied at Month 3)
- 1 empty bottle of FTC/TDF or placebo (bottle was re-issued at Month 3)
- 1 bottle containing 2 tablets of FTC/TDF or placebo (bottle was re-supplied at Month 1).

The site pharmacist should complete the first row as follows

	TDF or Placebo		AND FTC/TDF or Placebo		OR 1% Tenofovir Gel or Placebo
	Total Bottles	Total Tablets	Total Bottles	Total Tablets	Total Applicators
Quantity of product actually returned *For oral participants, include empty bottles in "Total Bottles" count.*	2	04	2	04	
Quantity of unused product **not** returned *Based on participant's self-report*					
Quantity of product expected to be returned					
Quantity of product available for re-issue					

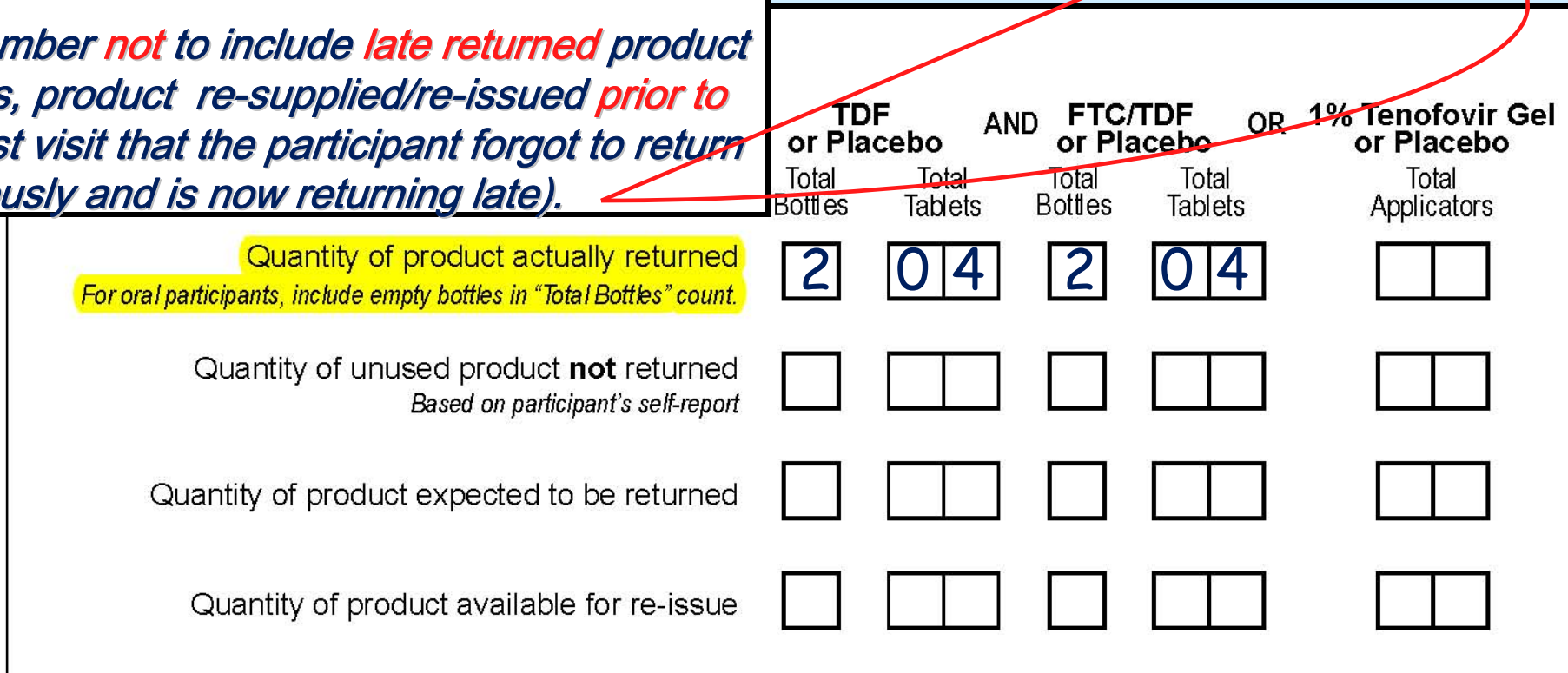
For example, at her Month 3 Visit a participant is dispensed the following:

- 1 bottle re-supply of TDF or placebo
- 1 bottle with 2 re-issued tablets of TDF or placebo
- 1 bottle re-supply of FTC/TDF or placebo
- 1 bottle with 2 re-issued tablets of FTC/TDF or placebo.

At her Month 4 Visit, she returns the following:

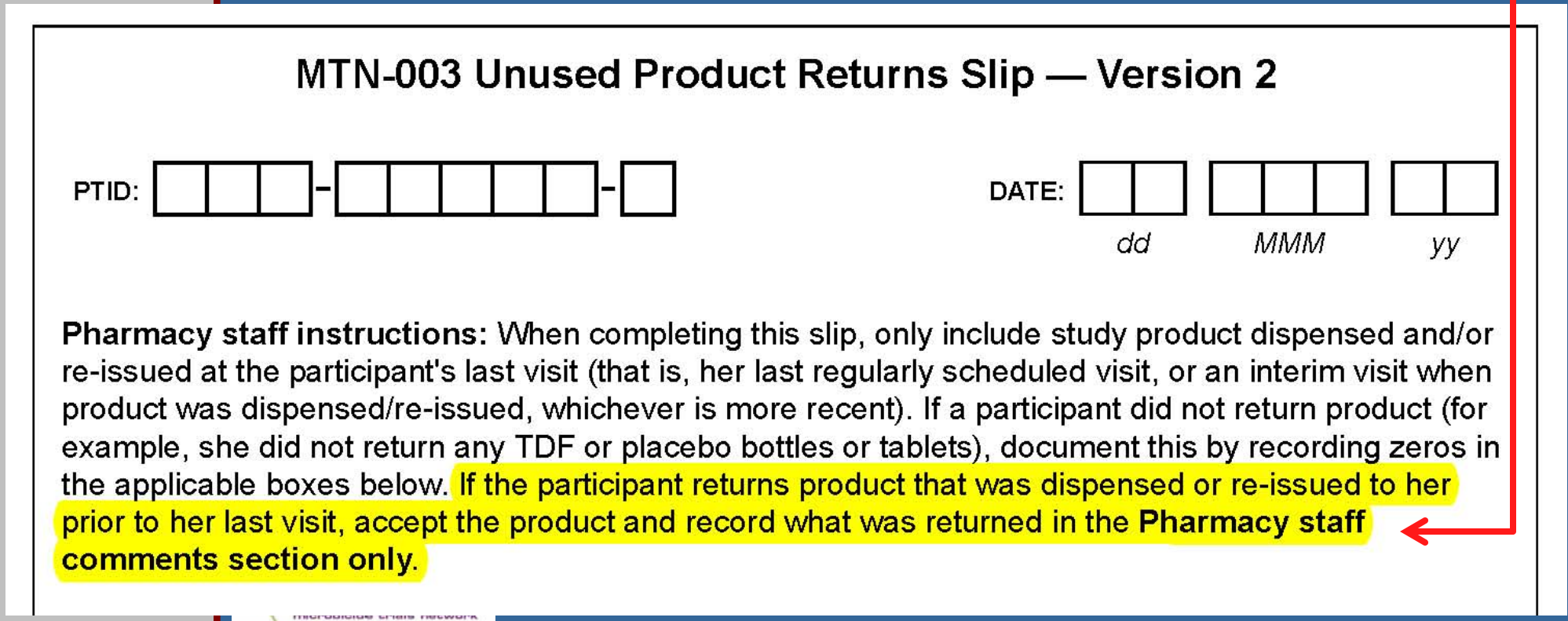
- 1 bottle containing 4 tablets of TDF or placebo (bottle was re-supplied at Month 3)
- 1 empty bottle of TDF or placebo (bottle was re-issued at Month 3)
- 1 bottle containing 2 tablets of TDF or placebo (bottle was re-supplied at Month 1)
- 1 bottle containing 4 tablets of FTC/TDF or placebo (bottle was re-supplied at Month 3)
- 1 empty bottle of FTC/TDF or placebo (bottle was re-issued at Month 3)
- 1 bottle containing 2 tablets of FTC/TDF or placebo (bottle was re-supplied at Month 1).

Remember not to include late returned product (that is, product re-supplied/re-issued prior to the last visit that the participant forgot to return previously and is now returning late).



There will be cases where a participant is expected to return product at a given visit, but fails to do so. If, at a subsequent visit, she returns the product she forgot/failed to return at a previous visit, the site pharmacist must record the late returned product in the comments section ONLY of the slip.

The pharmacist may also use the comments section to record any issues related to the returned product.



MTN-003 Unused Product Returns Slip — Version 2

PTID: ☐☐☐-☐☐☐☐☐-☐

DATE: ☐☐ ☐☐☐ ☐☐
dd MMM yy

Pharmacy staff instructions: When completing this slip, only include study product dispensed and/or re-issued at the participant's last visit (that is, her last regularly scheduled visit, or an interim visit when product was dispensed/re-issued, whichever is more recent). If a participant did not return product (for example, she did not return any TDF or placebo bottles or tablets), document this by recording zeros in the applicable boxes below. If the participant returns product that was dispensed or re-issued to her prior to her last visit, accept the product and record what was returned in the **Pharmacy staff comments section only.**

For the example we just reviewed, below is a sample note containing the information the pharmacist should record in the comments section.

Pharmacy Staff Comments:

In addition to the above, the participant returned the following:

- *1 bottle that was re-supplied at MONTH 1 containing 2 TDF or placebo tablets.*
- *1 bottle that was re-supplied at MONTH 1 containing 2 FTC/TDF or placebo tablets.*

RPh Initials/Date: *KP 30-AUG-10*

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PTID: ☐☐☐-☐☐☐☐☐-☐ DATE: ☐☐ ☐☐☐ ☐☐
dd *MMM* *yy*

Pharmacy staff instructions: When completing this slip, only include study product dispensed and/or re-issued at the participant's last visit (that is, her last regularly scheduled visit, or an interim visit when product was dispensed/re-issued, whichever is more recent). If a participant did not return product (for example, she did not return any TDF or placebo bottles or tablets), document this by recording zeros in the applicable boxes below. If the participant returns product that was dispensed or re-issued to her prior to her last visit, accept the product and record what was returned in the **Pharmacy staff**

If the participant did not return any product from the last visit, record zeros. For oral participants, the first row would look like this.

	TDF or Placebo		AND **FTC/TDF or Placebo**		OR **1% Tenofovir Gel or Placebo**
	Total Bottles	Total Tablets	Total Bottles	Total Tablets	Total Applicators
Quantity of product actually returned *For oral participants, include empty bottles in "Total Bottles" count.*	0	00	0	00	☐☐
Quantity of unused product **not** returned *Based on participant's self-report*	☐	☐☐	☐	☐☐	☐☐
Quantity of product expected to be returned	☐	☐☐	☐	☐☐	☐☐
Quantity of product available for re-issue	☐	☐☐	☐	☐☐	☐☐

MTN-003 Unused Product Returns Slip — Version 2

PTID: ☐☐☐-☐☐☐☐☐-☐ DATE: ☐☐ ☐☐☐ ☐☐
dd *MMM* *yy*

Pharmacy staff instructions: When completing this slip, only include study product dispensed and/or re-issued at the participant's last visit (that is, her last regularly scheduled visit, or an interim visit when product was dispensed/re-issued, whichever is more recent). If a participant did not return product (for example, she did not return any TDF or placebo bottles or tablets), document this by recording zeros in the applicable boxes below. If the participant returns product that was dispensed or re-issued to her prior to her last visit, accept the product and record what was returned in the **Pharmacy staff**

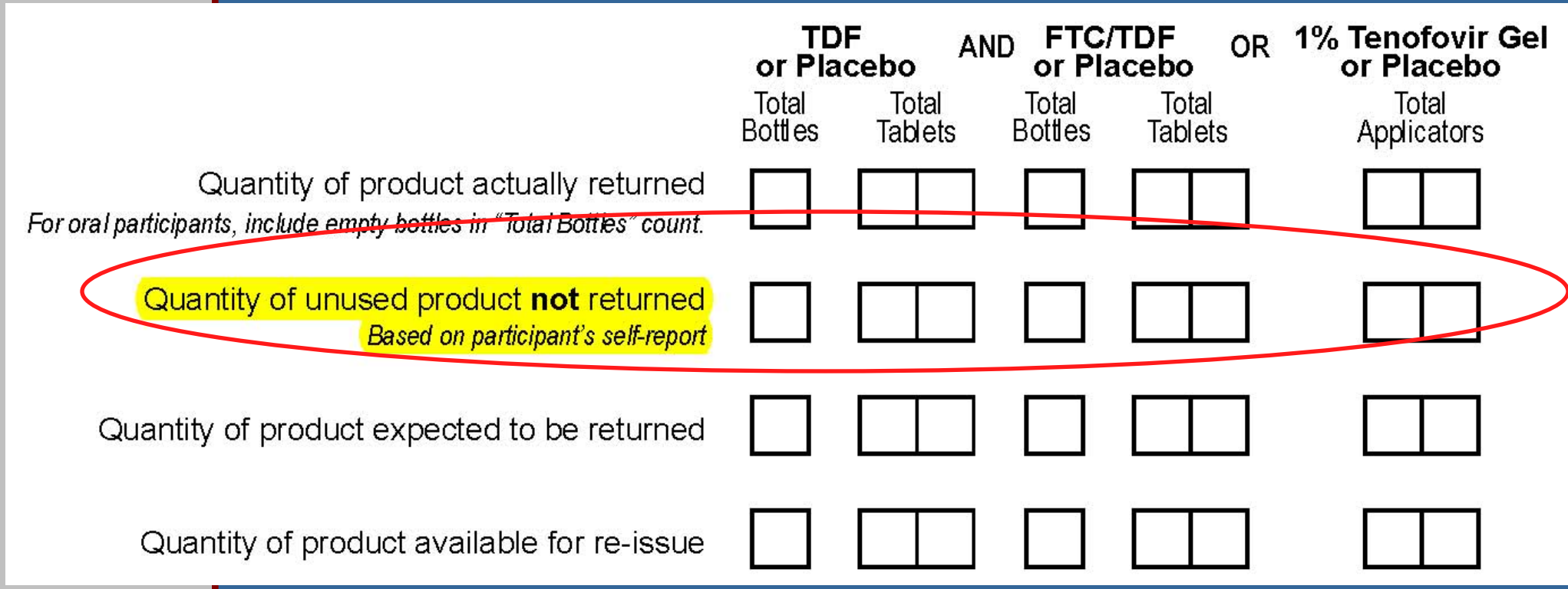
If the participant did not return any product from the last visit, record zeros. For vaginal participants, the first row would look like this.

	TDF or Placebo		AND **FTC/TDF or Placebo**		OR **1% Tenofovir Gel or Placebo**
	Total Bottles	Total Tablets	Total Bottles	Total Tablets	Total Applicators
Quantity of product actually returned *For oral participants, include empty bottles in "Total Bottles" count.*	☐	☐☐	☐	☐☐	0 0
Quantity of unused product **not** returned *Based on participant's self-report*	☐	☐☐	☐	☐☐	☐☐
Quantity of product expected to be returned	☐	☐☐	☐	☐☐	☐☐
Quantity of product available for re-issue	☐	☐☐	☐	☐☐	☐☐

MTN-003 Unused Product Returns Slip – Version 2

Assessing and documenting study product not returned

Ask the participant how much unused study product she left at home/forgot to return among product dispensed at her last visit. If no product was dispensed at her last visit, record zeros.



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Complete the second row based on participant report. If needed, the site pharmacist may remind the participant how much product (if any) she was re-supplied/re-issued at her last visit.

	TDF or Placebo		AND FTC/TDF or Placebo		OR 1% Tenofovir Gel or Placebo
	Total Bottles	Total Tablets	Total Bottles	Total Tablets	Total Applicators
Quantity of product actually returned *For oral participants, include empty bottles in "Total Bottles" count.*	☐	☐☐	☐	☐☐	☐☐
Quantity of unused product **not** returned *Based on participant's self-report*	☐	☐☐	☐	☐☐	☐☐
Quantity of product expected to be returned	☐	☐☐	☐	☐☐	☐☐
Quantity of product available for re-issue	☐	☐☐	☐	☐☐	☐☐

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MTN-003 Unused Product Returns Slip – Version 2

Calculating and documenting the quantity of study product expected to be returned

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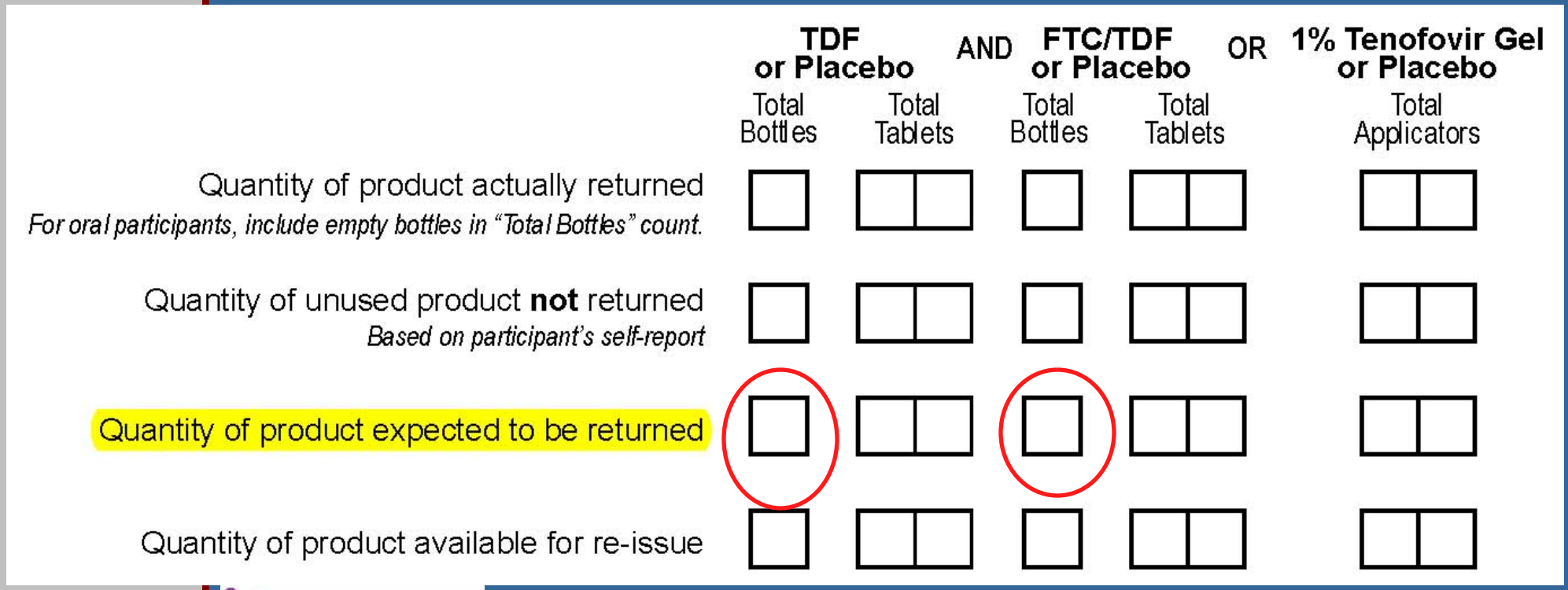
At interim visits, unused product should be collected from participants and returned to the site pharmacy ONLY if:

- product needs to be re-supplied/re-issued at the visit (e.g., to resume product use after a hold, or to replace lost/damaged product), or
- a product return is warranted due to a product hold/discontinuation.

If unused product is collected at an interim visit, both a MTN-003 Unused Product Returns Slip and the Product Returns form should be completed. (An MTN-003 Study Product Request Slip should also be completed).

For oral participants, the "Total Bottles" expected to be returned =the total # bottles that were re-supplied and re-issued at the last visit. If no bottles were re-supplied or re-issued at the last visit, record zeros.



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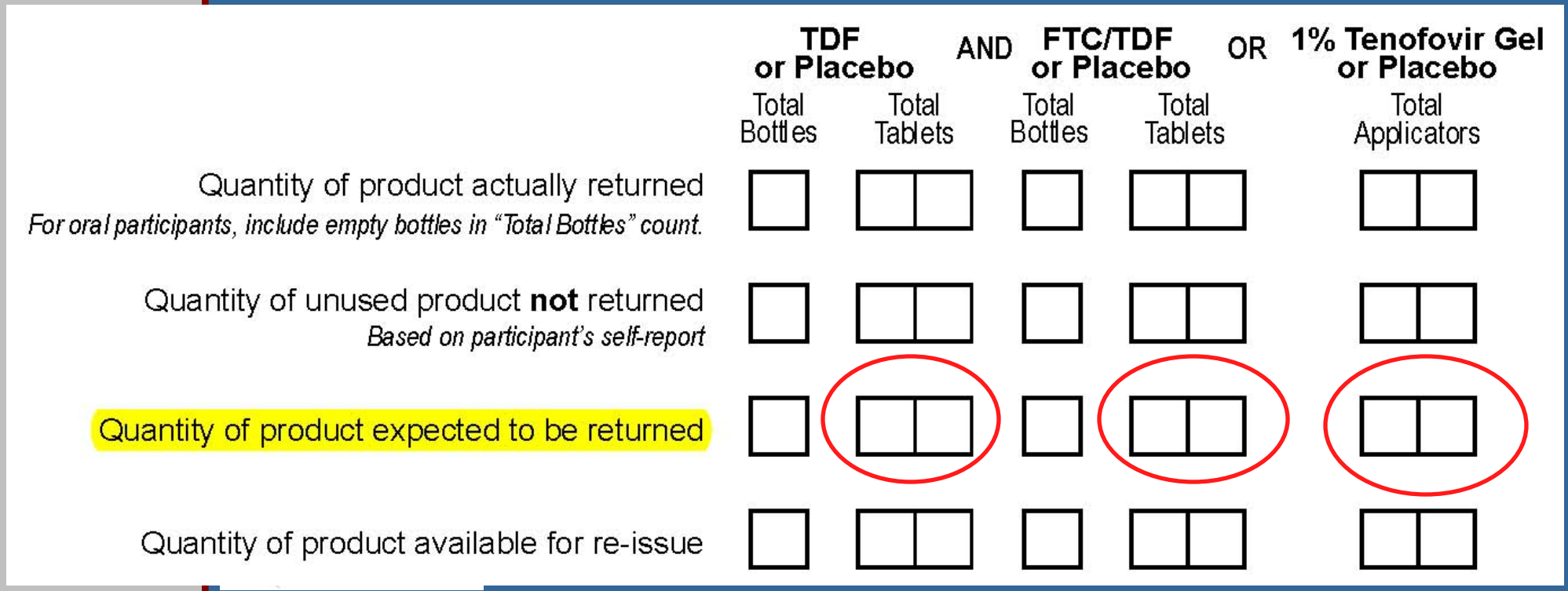
Calculate the quantity of tablets/applicators expected to be returned as follows:

\# tablets/applicators re-supplied and re-issued at last visit
\- # days participant expected to use product since last visit

---

= quantity of product expected to be returned



Note: Even if a participant is expected to have used all tablets in a bottle, she is still expected to return the empty bottle.

	TDF or Placebo		AND FTC/TDF or Placebo		OR 1% Tenofovir Gel or Placebo
	Total Bottles	Total Tablets	Total Bottles	Total Tablets	Total Applicators
Quantity of product actually returned *For oral participants, include empty bottles in "Total Bottles" count.*	☐	☐☐	☐	☐☐	☐☐
Quantity of unused product **not** returned *Based on participant's self-report*	☐	☐☐	☐	☐☐	☐☐
Quantity of product expected to be returned	☐	☐☐	☐	☐☐	☐☐
Quantity of product available for re-issue	☐	☐☐	☐	☐☐	☐☐

Note: do not count days on site-initiated product hold/discontinuation when counting the # days the participant is expected to use product since her last visit.

	TDF or Placebo		AND FTC/TDF or Placebo		OR 1% Tenofovir Gel or Placebo
	Total Bottles	Total Tablets	Total Bottles	Total Tablets	Total Applicators
Quantity of product actually returned *For oral participants, include empty bottles in "Total Bottles" count.*	☐	☐☐	☐	☐☐	☐☐
Quantity of unused product **not** returned *Based on participant's self-report*	☐	☐☐	☐	☐☐	☐☐
Quantity of product expected to be returned	☐	☐☐	☐	☐☐	☐☐
Quantity of product available for re-issue	☐	☐☐	☐	☐☐	☐☐

Example: at her Month 2 Visit a participant is dispensed the following:

- 1 bottle re-supply of TDF or placebo
- 1 bottle with 2 re-issued tablets of TDF or placebo
- 1 bottle re-supply of FTC/TDF or placebo
- 1 bottle with 2 re-issued tablets of FTC/TDF or placebo.

On the day of her Month 3 Visit, she is expected to have used study product for 28 days.

At this participant's Month 3 Visit, how should the site pharmacist complete the third row of the slip?

	TDF or Placebo		AND	**FTC/TDF or Placebo**		OR	**1% Tenofovir Gel or Placebo**
	Total Bottles	Total Tablets		Total Bottles	Total Tablets		Total Applicators
Quantity of product actually returned *For oral participants, include empty bottles in "Total Bottles" count.*	☐	☐☐		☐	☐☐		☐☐
Quantity of unused product **not** returned *Based on participant's self-report*	☐	☐☐		☐	☐☐		☐☐
Quantity of product expected to be returned	☐	☐☐		☐	☐☐		☐☐
Quantity of product available for re-issue	☐	☐☐		☐	☐☐		☐☐

For example, at her Month 2 Visit a participant is dispensed the following:

- 1 bottle re-supply of TDF or placebo
- 1 bottle with 2 re-issued tablets of TDF or placebo
- 1 bottle re-supply of FTC/TDF or placebo
- 1 bottle with 2 re-issued tablets of FTC/TDF or placebo.

On the day of her Month 3 Visit, she is expected to have used study product for 28 days.

The site pharmacist should complete the third row as follows (32-28=4 tablets)

	TDF or Placebo		AND	FTC/TDF or Placebo		OR	1% Tenofovir Gel or Placebo
	Total Bottles	Total Tablets		Total Bottles	Total Tablets		Total Applicators
Quantity of product actually returned *For oral participants, include empty bottles in "Total Bottles" count.*							
Quantity of unused product **not** returned *Based on participant's self-report*							
Quantity of product expected to be returned	2	04		2	04		
Quantity of product available for re-issue							

MTN-003 Unused Product Returns Slip – Version 2

Assessing and documenting the quantity of study product available for re-issue

MTN microbicide trials network

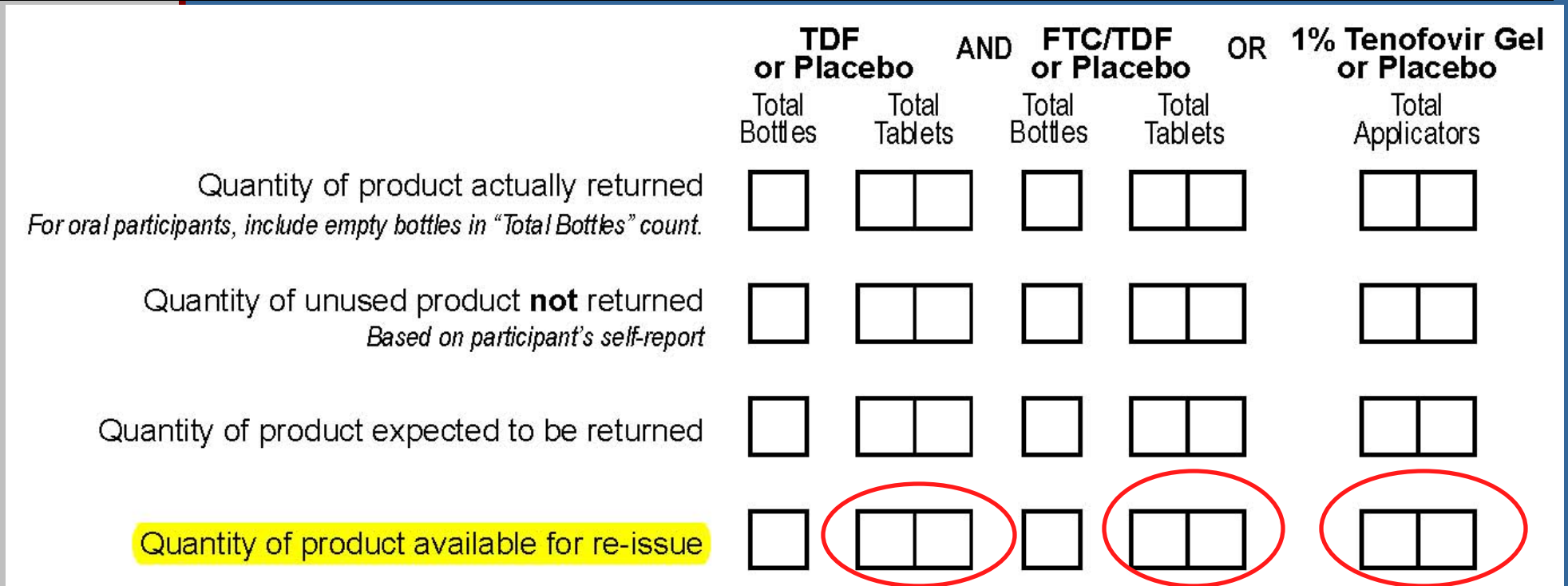
Statistical Center for HIV/AIDS Research & Prevention SCHARP

First, determine the quantity of tablets/applicators available for re-issue. This is equal to

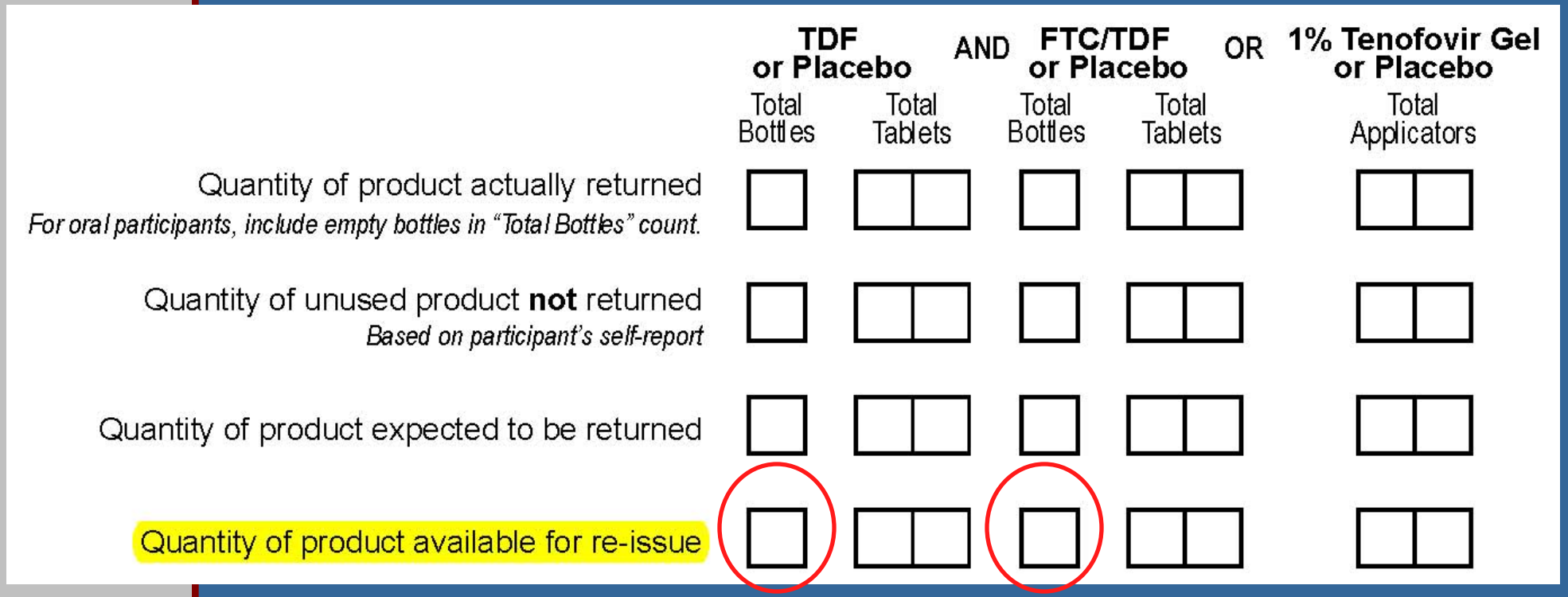
- the # tablets/applicators recorded in row 1 *that are determined to be in good condition – OR -*
- the # days left before the tablets/applicators expire,

whichever number is less.

Record the amount in the fourth row.



For oral participants, the "Total Bottles" available for re-issue is equal to the "Total Bottles" in row 1 that contain study tablets available for re-issue.



MTN microbicide trials network

Statistical Center for HIV/AIDS Research & Prevention SCHARP

For example, a participant is given the following at her Month 2 Visit:

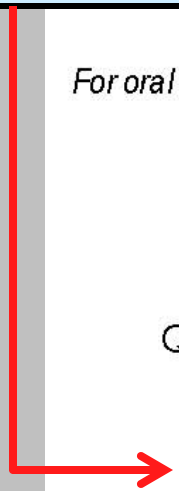
- TDF or placebo: 1 bottle re-supply, and 1 bottle re-issue with 2 tablets
- FTC/TDF or placebo: 1 bottle re-supply, and 1 bottle re-issue with 2 tablets

At her Month 3 Visit, she returns *in good condition:*

- 1 bottle with 2 tablets of TDF or placebo (bottle was re-supplied at Month 2)
- 1 empty bottle of TDF or placebo (bottle was re-issued at Month 2)
- 1 bottle with 2 tablets of FTC/TDF or placebo (bottle was re-supplied at Month 2)
- 1 empty bottle of FTC/TDF or placebo (bottle was re-issued at Month 2).

She completes her Month 3 Visit exactly 31 days later and is expected to have used 31 doses of study product since her last visit.

At this participant's Month 3 Visit, how should the site pharmacist complete the fourth row of the slip?



	TDF or Placebo		AND FTC/TDF or Placebo		OR 1% Tenofovir Gel or Placebo
	Total Bottles	Total Tablets	Total Bottles	Total Tablets	Total Applicators
Quantity of product actually returned *For oral participants, include empty bottles in "Total Bottles" count.*	2	02	2	02	
Quantity of unused product **not** returned *Based on participant's self-report*	0	00	0	00	
Quantity of product expected to be returned	2	01	2	01	
Quantity of product available for re-issue					

For example, a participant is given the following at her Month 2 Visit:

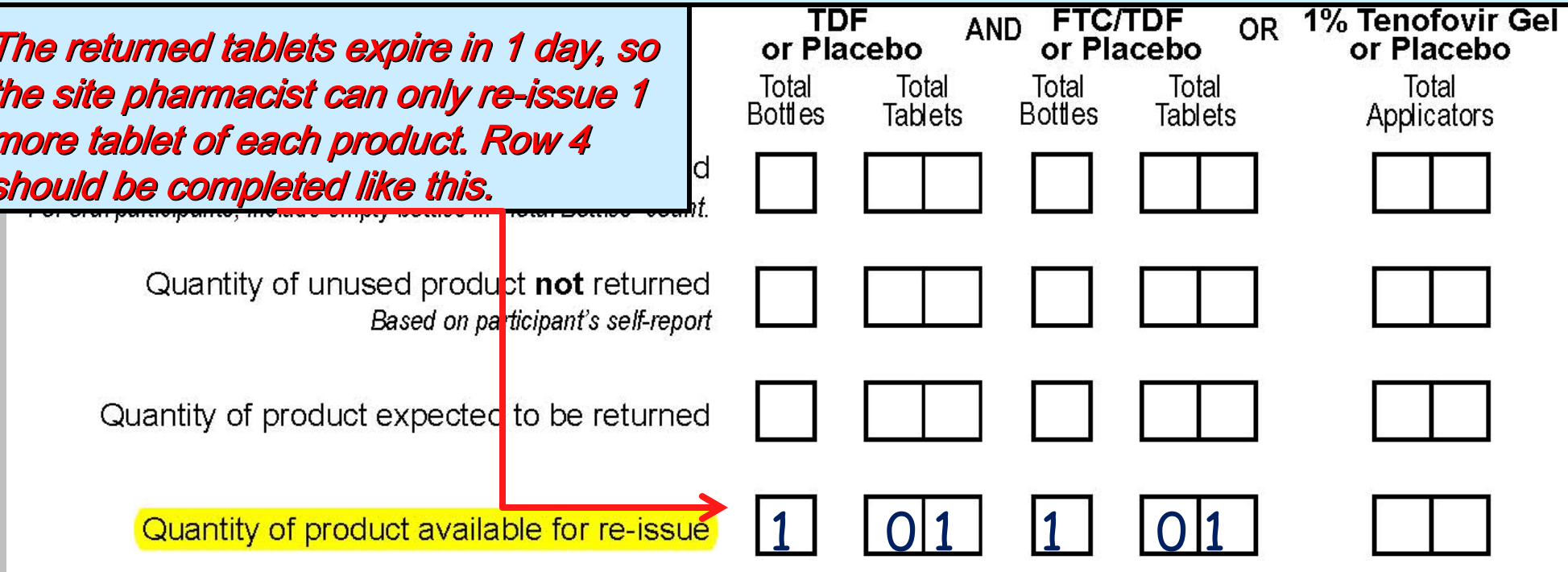
- TDF or placebo: 1 bottle re-supply, and 1 bottle re-issue with 2 tablets
- FTC/TDF or placebo: 1 bottle re-supply, and 1 bottle re-issue with 2 tablets

At her Month 3 Visit, she returns *in good condition:*

- 1 bottle with 2 tablets of TDF or placebo (bottle was re-supplied at Month 2)
- 1 empty bottle of TDF or placebo (bottle was re-issued at Month 2)
- 1 bottle with 2 tablets of FTC/TDF or placebo (bottle was re-supplied at Month 2)
- 1 empty bottle of FTC/TDF or placebo (bottle was re-issued at Month 2).

She completes her Month 3 Visit exactly 31 days later and is expected to have used 31 doses of study product since her last visit.

The returned tablets expire in 1 day, so the site pharmacist can only re-issue 1 more tablet of each product. Row 4 should be completed like this.



Remember:

- Oral study product expires 30 days after the bottle is opened.
- Vaginal study product expires 60 days after the initial dispensation date.

MTN-003 (VOICE)
Product Returns CRF

Product Returns CRF

- **Completed (preferably) by site clinic staff**
  - **At every monthly study visit through the PUEV**
  - **At every interim visit when:**
    - **product is returned to the pharmacy due to product hold/discontinuation – OR -**
    - **product is re-supplied/re-issued, even if no product is returned at the interim visit.**
- **Completed entirely based on transcription from the MTN-003 Unused Product Returns Slip**

MTN microbicide trials network

Statistical Center for HIV/AIDS Research & Prevention SCHARP

Product Returns CRF

Statistical Center for HIV/AIDS Research & Prevention (SCHARP) — Product Returns (PRT-1)

SAMPLE: DO NOT FAX TO DATAFAX

MTN003 VOICE (160) PRT-1 (079) Visit Code ☐☐.☐ 1

Page 1 of 1

Participant ID ☐☐☐-☐☐☐☐-☐ (Site Number – Participant Number – Chk)

Product Returns

Visit Date ☐☐ dd ☐☐☐ MMM ☐☐ yy

If the participant is randomized to vaginal study product, go to item 5.

ORAL PRODUCTS RETURNED

	# bottles returned	# tablets returned
1. Returned **TDF or placebo**:	☐	☐☐
2. Returned **FTC/TDF or placebo**:	☐	☐☐
	# bottles **not** returned	# tablets **not** returned
3. Unused **TDF or placebo** not returned:	☐	☐☐
4. Unused **FTC/TDF or placebo** not returned:	☐	☐☐ → ***End of form.***

VAGINAL PRODUCTS RETURNED

	# applicators returned
5. Returned **unused applicators**:	☐☐
	# applicators **not** returned
6. **Unused applicators** not returned:	☐☐

Comments: _____

☐☐☐☒ 12-AUG-10

/networks/hivnet/forms/MTN_003/forms/m003_PRT.fm

01 Language _____ Staff Initials / Date

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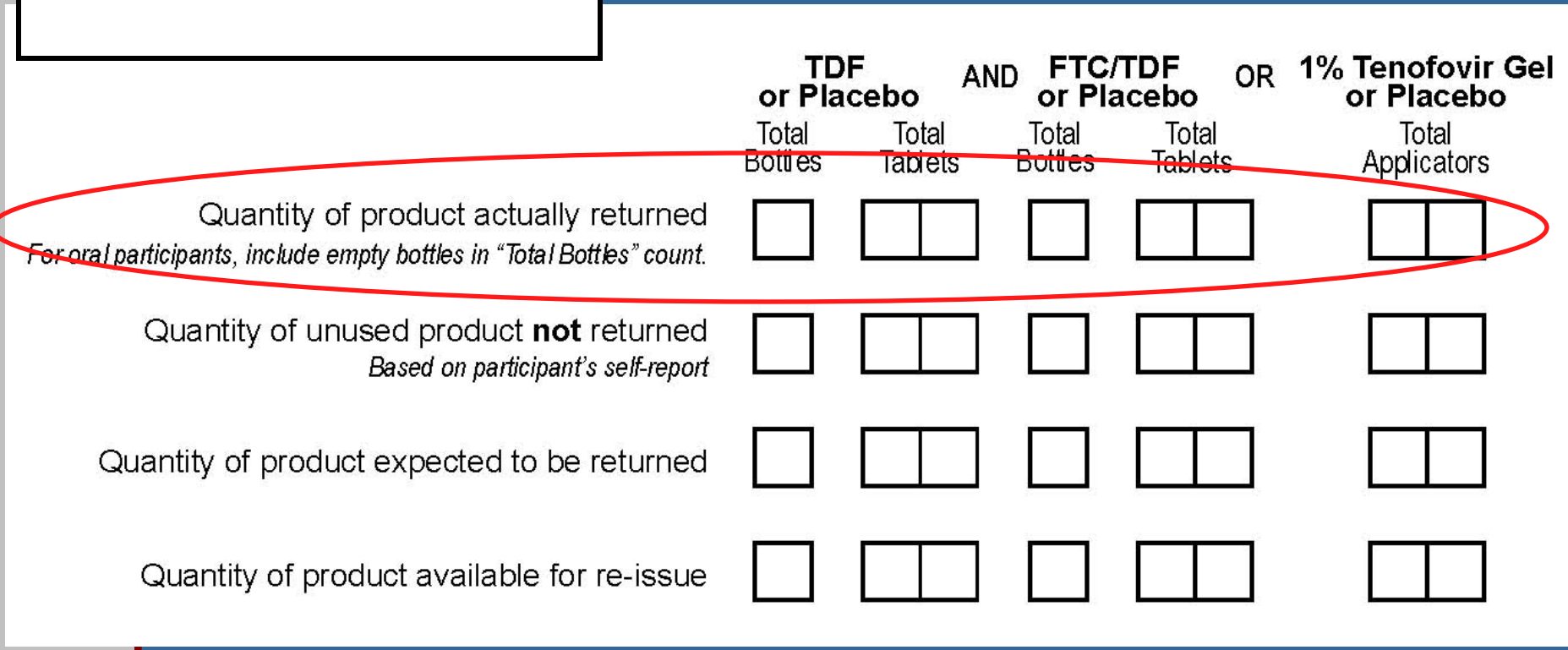
To complete the Product Returns CRF, transcribe as follows...

Data from row 1 of the slip



	TDF or Placebo		AND FTC/TDF or Placebo		OR 1% Tenofovir Gel or Placebo
	Total Bottles	Total Tablets	Total Bottles	Total Tablets	Total Applicators
Quantity of product actually returned *For oral participants, include empty bottles in "Total Bottles" count.*	☐	☐☐	☐	☐☐	☐☐
Quantity of unused product **not** returned *Based on participant's self-report*	☐	☐☐	☐	☐☐	☐☐
Quantity of product expected to be returned	☐	☐☐	☐	☐☐	☐☐
Quantity of product available for re-issue	☐	☐☐	☐	☐☐	☐☐

...is transcribed onto items 1 and 2 of the form *for oral participants* ...

Participant ID ☐☐☐-☐☐☐☐☐-☐ (Site Number / Participant Number / Chk)

Product Returns

Visit Date ☐☐ ☐☐☐ ☐☐ (*dd* / *MMM* / *yy*)

If the participant is randomized to vaginal study product, go to item 5.

ORAL PRODUCTS RETURNED

		# bottles returned	*# tablets returned*
1.	Returned **TDF or placebo**:	☐	☐☐
2.	Returned **FTC/TDF or placebo**:	☐	☐☐
3.	Unused **TDF or placebo** not returned:	☐	☐☐
4.	Unused **FTC/TDF or placebo** not returned:	☐	☐☐ → ***End of form.***

*# bottles **not** returned* / *# tablets **not** returned*

VAGINAL PRODUCTS RETURNED

5.	Returned **unused applicators**:	*# applicators returned* ☐☐
6.	**Unused applicators** not returned:	*# applicators **not** returned* ☐☐

... and is transcribed onto item 5 of the form *for vaginal participants*.

Participant ID

Site Number - Participant Number - Chk

Product Returns

Visit Date

dd *MMM* *yy*

If the participant is randomized to vaginal study product, go to item 5.

ORAL PRODUCTS RETURNED

		# bottles returned	# tablets returned
1.	Returned **TDF or placebo**:		

		# bottles returned	# tablets returned
2.	Returned **FTC/TDF or placebo**:		

		# bottles ***not*** returned	# tablets ***not*** returned
3.	Unused **TDF or placebo** not returned:		

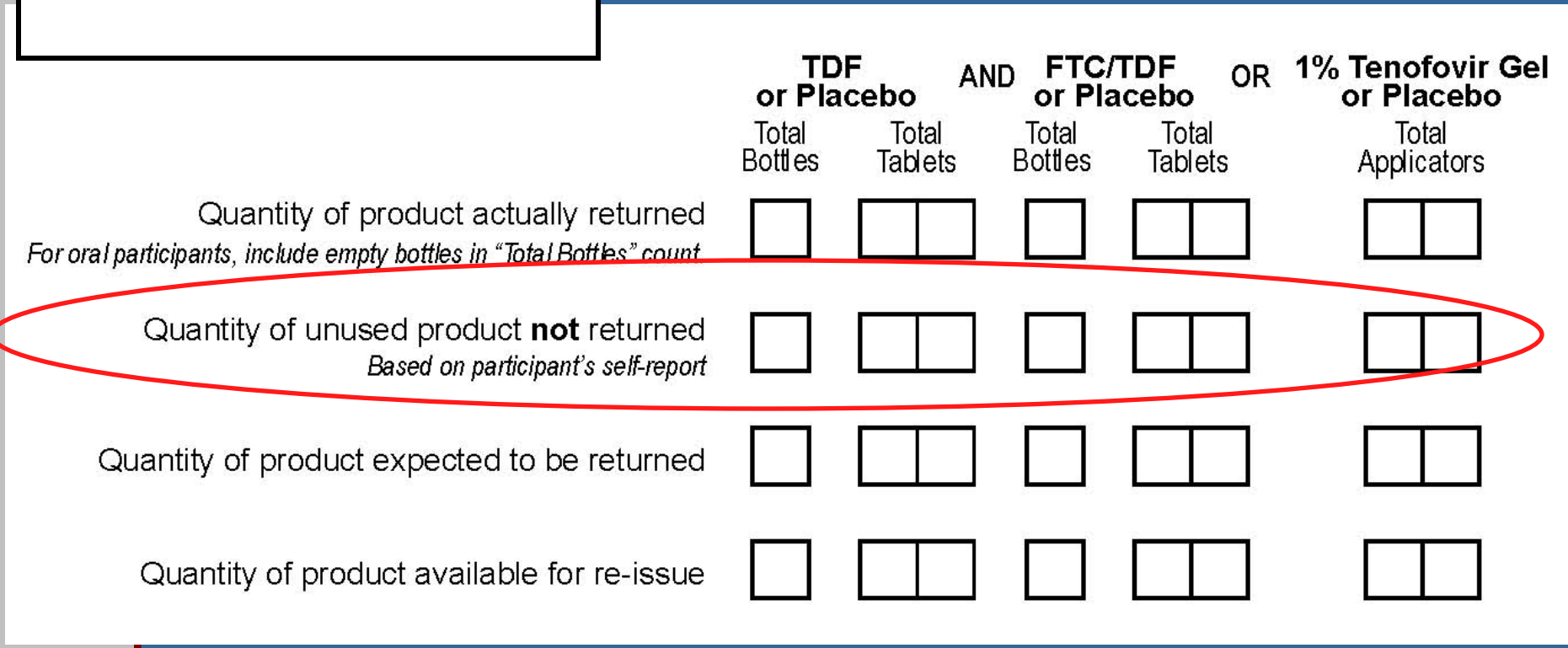
		# bottles ***not*** returned	# tablets ***not*** returned	
4.	Unused **FTC/TDF or placebo** not returned:			→ ***End of form.***

VAGINAL PRODUCTS RETURNED

		# applicators returned
5.	Returned **unused applicators**:	

		# applicators ***not*** returned
6.	**Unused applicators** not returned:	

Data from row 2 of the slip



	TDF or Placebo		AND FTC/TDF or Placebo		OR 1% Tenofovir Gel or Placebo
	Total Bottles	Total Tablets	Total Bottles	Total Tablets	Total Applicators
Quantity of product actually returned *For oral participants, include empty bottles in "Total Bottles" count*	☐	☐☐	☐	☐☐	☐☐
Quantity of unused product **not** returned *Based on participant's self-report*	☐	☐☐	☐	☐☐	☐☐
Quantity of product expected to be returned	☐	☐☐	☐	☐☐	☐☐
Quantity of product available for re-issue	☐	☐☐	☐	☐☐	☐☐

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Statistical Center for HIV/AIDS Research & Prevention SCHARP

...is transcribed onto items 3 and 4 of the form *for oral participants* ...

Participant ID ☐☐☐-☐☐☐☐☐-☐ (Site Number / Participant Number / Chk)

Product Returns

Visit Date ☐☐ ☐☐☐ ☐☐ (*dd* / *MMM* / *yy*)

If the participant is randomized to vaginal study product, go to item 5.

ORAL PRODUCTS RETURNED

		# bottles returned	# tablets returned	
1.	Returned **TDF or placebo**:	☐	☐☐	
2.	Returned **FTC/TDF or placebo**:	☐	☐☐	
		# bottles ***not*** returned	# tablets ***not*** returned	
3.	Unused **TDF or placebo** not returned:	☐	☐☐	
4.	Unused **FTC/TDF or placebo** not returned:	☐	☐☐ →	***End of form.***

VAGINAL PRODUCTS RETURNED

		# applicators returned
5.	Returned **unused applicators**:	☐☐
		# applicators ***not*** returned
6.	**Unused applicators** not returned:	☐☐

... and is transcribed onto item 6 of the form *for vaginal participants*.

Participant ID ☐☐☐-☐☐☐☐☐-☐ (Site Number / Participant Number / Chk)

Product Returns

Visit Date ☐☐ ☐☐☐ ☐☐ (*dd* / *MMM* / *yy*)

If the participant is randomized to vaginal study product, go to item 5.

ORAL PRODUCTS RETURNED

		# bottles returned	*# tablets returned*
1.	Returned **TDF or placebo**:	☐	☐☐
2.	Returned **FTC/TDF or placebo**:	☐	☐☐
3.	Unused **TDF or placebo** not returned:	☐	☐☐
4.	Unused **FTC/TDF or placebo** not returned:	☐	☐☐ → ***End of form.***

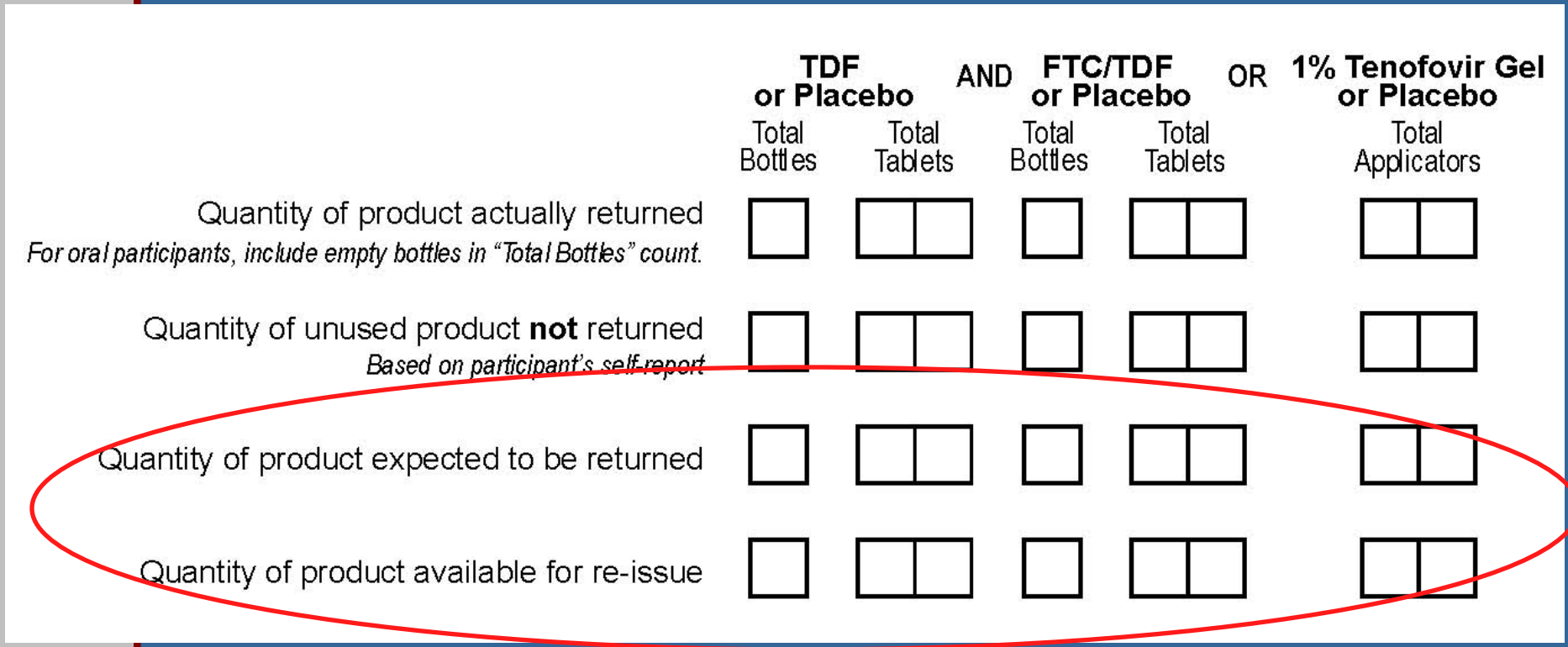
*# bottles **not** returned* / *# tablets **not** returned*

VAGINAL PRODUCTS RETURNED

		# applicators returned
5.	Returned **unused applicators**:	☐☐
6.	**Unused applicators** not returned:	☐☐

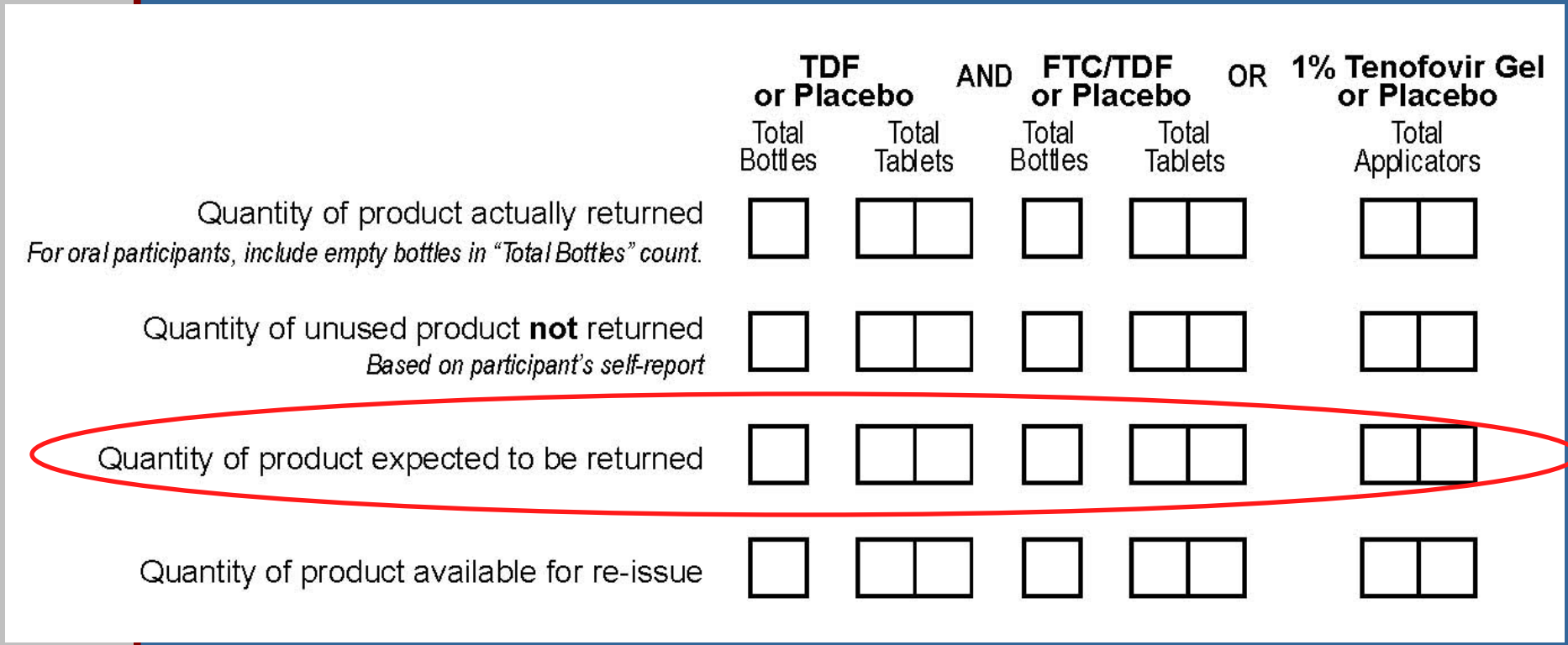
*# applicators **not** returned*

Data from rows 3 and 4 of the slip are not transcribed onto the Product Returns CRF.



	TDF or Placebo		AND FTC/TDF or Placebo		OR 1% Tenofovir Gel or Placebo
	Total Bottles	Total Tablets	Total Bottles	Total Tablets	Total Applicators
Quantity of product actually returned *For oral participants, include empty bottles in "Total Bottles" count.*	☐	☐☐	☐	☐☐	☐☐
Quantity of unused product **not** returned *Based on participant's self-report*	☐	☐☐	☐	☐☐	☐☐
Quantity of product expected to be returned	☐	☐☐	☐	☐☐	☐☐
Quantity of product available for re-issue	☐	☐☐	☐	☐☐	☐☐

Data from row 3 is used for site reference (along with the slip comments) when counseling participants on product adherence at the pharmacy and clinic.



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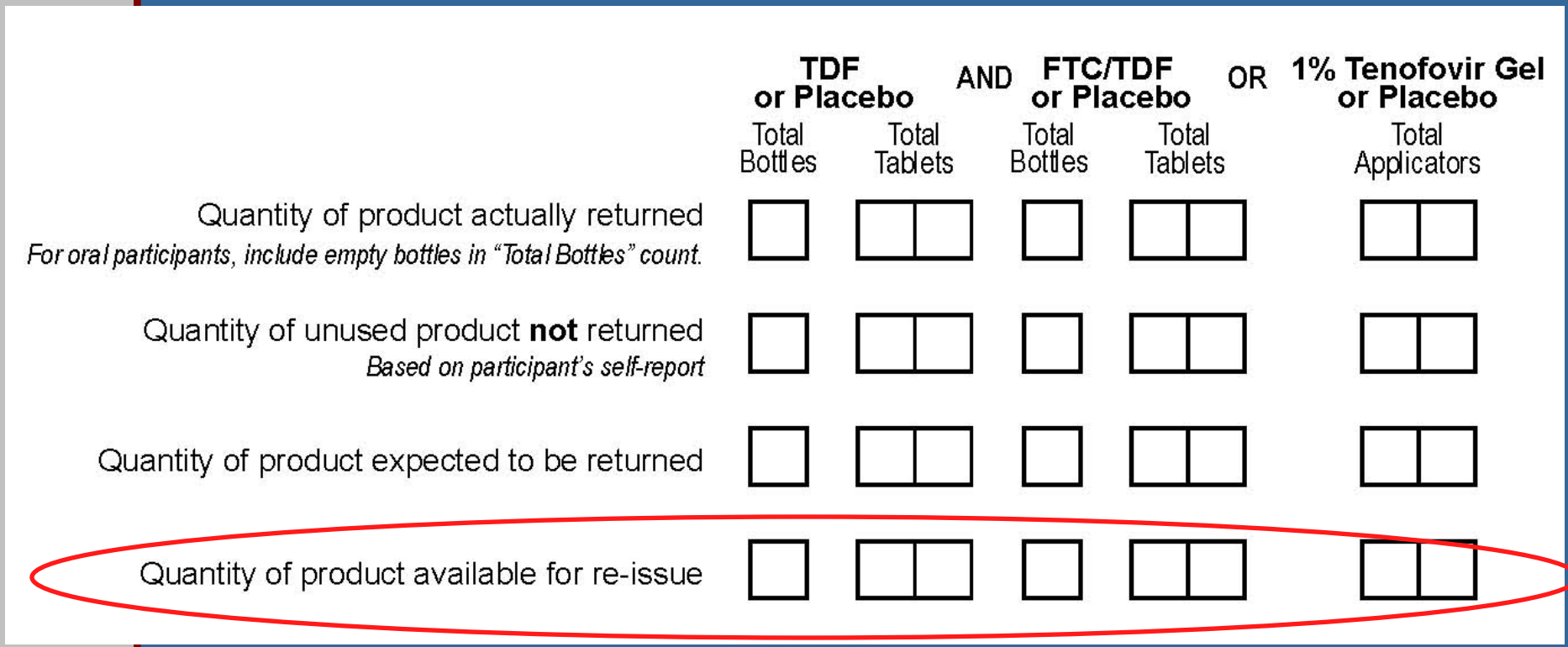
Data from row 4 is used for reference by the site's authorized prescriber to determine how much product to order for re-supply and re-issue.



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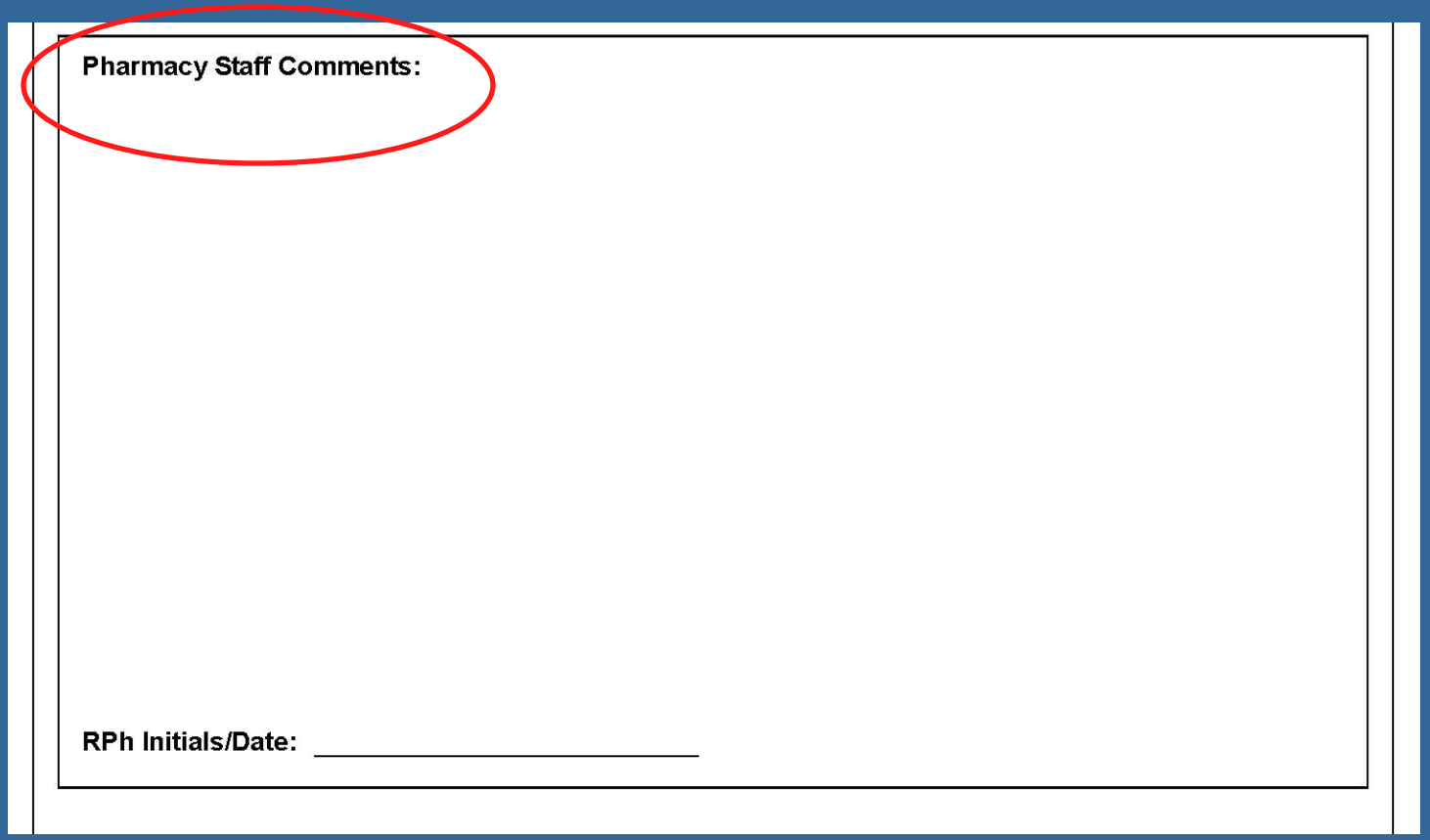
Data from the slip comments section...



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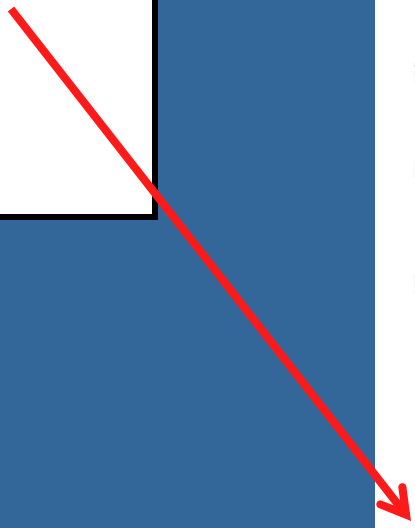
is transcribed onto the form comments section.



Participant ID

Site Number | Participant Number | Chk

Product Returns

Visit Date

dd | MMM | yy

If the participant is randomized to vaginal study product, go to item 5.

ORAL PRODUCTS RETURNED

		# bottles returned	# tablets returned
1.	Returned **TDF or placebo**:		
2.	Returned **FTC/TDF or placebo**:		
		# bottles **not** returned	# tablets **not** returned
3.	Unused **TDF or placebo** not returned:		
4.	Unused **FTC/TDF or placebo** not returned:		→ ***End of form.***

VAGINAL PRODUCTS RETURNED

		# applicators returned
5.	Returned **unused applicators**:	
		# applicators **not** returned
6.	**Unused applicators** not returned:	

Comments: _____

_____

_____

When counseling oral participants on product adherence, remember to:

- *Encourage participants to keep tablets in their original bottle (i.e., avoid combining tablets into one bottle)*
- *Advise participants to keep a bottle (and not throw it away), even if all tablets in it were used and it is empty*
- *Remind participants to return all bottles, including empty bottles, to each and every study visit*
  - *including interim visits, in case a hold/discontinuation is implemented at an interim visit that warrants collection of unused product*
- *Remind participants to use all re-issued tablets first, before opening a new bottle*
- *Remind participants not to use any product left at home, and to return it at the next visit*

When counseling vaginal participants on product adherence, remember to:

- *Remind participants to return all unused applicators to each and every study visit*
  - *including interim visits, in case a hold/discontinuation is implemented at an interim visit that warrants collection of unused product*
- *Remind participants to use all re-issued applicators first, before opening a new carton*
- *Remind participants not to use any product left at home, and to return all unused applicators, including unopened cartons, at the next visit*

MTN microbicide trials network

Statistical Center for HIV/AIDS Research & Prevention SCHARP

Scenarios for Group Discussion

SCENARIO #1a:

At her Month 2 Visit, a participant is dispensed the following:

- 1 bottle re-supply of TDF or placebo
- 1 bottle with 4 re-issued tablets of TDF or placebo
- 1 bottle re-supply of FTC/TDF or placebo
- 1 bottle with 4 re-issued tablets of FTC/TDF or placebo.

At her Month 3 Visit, she returns the following:

- 1 bottle containing 7 tablets of TDF or placebo (bottle was re-supplied at Month 2)
- 1 bottle containing 7 tablets of FTC/TDF or placebo (bottle was re-supplied at Month 2).

She states that she threw away the empty re-issued bottles and has no unused bottles or tablets left at home.

QUESTIONS:

1.What should the site pharmacist record in rows 1 and 2 of the slip?

2.What should site staff record for items 1-4 of the form?

SCENARIO #1a: ANSWER

Empty bottles were not returned

	TDF or Placebo		AND FTC/TDF or Placebo		OR 1% Tenofovir Gel or Placebo
	Total Bottles	Total Tablets	Total Bottles	Total Tablets	Total Applicators
Quantity of product actually returned *For oral participants, include empty bottles in "Total Bottles" count.*	1	07	1	07	
Quantity of unused product **not** returned *Based on participant's self-report*	1	00	1	00	
Quantity of product expected to be returned					
Quantity of product available for re-issue					

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SCENARIO #1a: ANSWER

Participant ID: [ ][ ][ ] - [ ][ ][ ][ ][ ] - [ ]
Site Number — Participant Number — Chk

Product Returns

Visit Date: [ ][ ] [ ][ ][ ] [ ][ ]
dd — MMM — yy

If the participant is randomized to vaginal study product, go to item 5.

ORAL PRODUCTS RETURNED

		# bottles returned	# tablets returned
1.	Returned **TDF or placebo**:	1	07
2.	Returned **FTC/TDF or placebo**:	1	07
3.	Unused **TDF or placebo** not returned:	1	00
4.	Unused **FTC/TDF or placebo** not returned:	1	00 → ***End of form.***

(# bottles **not** returned / # tablets **not** returned)

VAGINAL PRODUCTS RETURNED

		# applicators returned
5.	Returned **unused applicators**:	[ ][ ]
6.	**Unused applicators** not returned:	[ ][ ]

(# applicators **not** returned)

SCENARIO #1b:

At her Month 2 Visit, a participant is dispensed the following:

- 1 bottle re-supply of TDF or placebo
- 1 bottle with 4 re-issued tablets of TDF or placebo
- 1 bottle re-supply of FTC/TDF or placebo
- 1 bottle with 4 re-issued tablets of FTC/TDF or placebo.

At her Month 3 Visit, she returns the following determined to be in good condition:

- 1 bottle containing 7 tablets of TDF or placebo (bottle was re-supplied at Month 2)
- 1 bottle containing 7 tablets of FTC/TDF or placebo (bottle was re-supplied at Month 2).

She states that she threw away the empty re-issued bottles and has no unused bottles or tablets left at home.

The participant completed her Month 2 Visit 29 days ago and is expected to have used study product for 29 days since her last visit.

QUESTION:

1.What should the site pharmacist record in rows 3 and 4 of the slip?

SCENARIO #1b: ANSWER

Can only re-issue 5 of the 7 returned tablets, since the returned tablets expire in 5 days.

	TDF or Placebo		AND	FTC/TDF or Placebo		OR	1% Tenofovir Gel or Placebo
	Total Bottles	Total Tablets		Total Bottles	Total Tablets		Total Applicators
Quantity of product actually returned *For oral participants, include empty bottles in "Total Bottles" count.*							
Quantity of unused product **not** returned *Based on participant's self-report*							
Quantity of product expected to be returned	2	05		2	05		
Quantity of product available for re-issue	1	05		1	05		

MTN microbicide trials network

Statistical Center for HIV/AIDS Research & Prevention SCHARP

SCENARIO #2a:

At her Month 6 Visit, a participant is dispensed the following:

- 1 bottle re-supply of TDF or placebo
- 1 bottle re-supply of FTC/TDF or placebo.

At her Month 7 Visit, she returns the following:

- 1 bottle containing 4 tablets of FTC/TDF or placebo (bottle was re-supplied at Month 6).

She states that she had one other bottle of TDF or placebo tablets left with 4 tablets in it, but the tablets spilled on the ground when she was walking to the clinic, so she threw them and the bottle away.

QUESTIONS:

1.What should the site pharmacist record in rows 1 and 2 of the slip?

2.What should site staff record for items 1-4 of the form?

SCENARIO #2a: ANSWER

	TDF or Placebo		AND	FTC/TDF or Placebo		OR	1% Tenofovir Gel or Placebo
	Total Bottles	Total Tablets		Total Bottles	Total Tablets		Total Applicators
Quantity of product actually returned *For oral participants, include empty bottles in "Total Bottles" count.*	0	00		1	04		
Quantity of unused product **not** returned *Based on participant's self-report*	1	04		0	00		
Quantity of product expected to be returned							
Quantity of product available for re-issue							

SCENARIO #2a: ANSWER

Participant ID

[ ][ ][ ] - [ ][ ][ ][ ][ ] - [ ]

Site Number | Participant Number | Chk

Product Returns

Visit Date

[ ][ ] [ ][ ][ ] [ ][ ]

dd *MMM* *yy*

If the participant is randomized to vaginal study product, go to item 5.

ORAL PRODUCTS RETURNED

		# bottles returned	*# tablets returned*
1.	Returned **TDF or placebo**:	0	0 0
2.	Returned **FTC/TDF or placebo**:	1	0 4
3.	Unused **TDF or placebo** not returned:	*# bottles **not** returned* 1	*# tablets **not** returned* 0 4
4.	Unused **FTC/TDF or placebo** not returned:	*# bottles **not** returned* 0	*# tablets **not** returned* 0 0 → ***End of form.***

VAGINAL PRODUCTS RETURNED

		# applicators returned
5.	Returned **unused applicators**:	[ ][ ]
6.	**Unused applicators** not returned:	*# applicators **not** returned* [ ][ ]

SCENARIO #2b:

At her Month 6 Visit, a participant is dispensed the following:

- 1 bottle re-supply of TDF or placebo
- 1 bottle re-supply of FTC/TDF or placebo.

At her Month 7 Visit, she returns the following determined to be in good condition:

- 1 bottle containing 4 tablets of FTC/TDF or placebo (bottle was re-supplied at Month 6).

She states that she had one other bottle of TDF or placebo tablets left with 4 tablets in it, but the tablets spilled on the ground when she was walking to the clinic, so she threw them and the bottle away.

The participant completed her Month 6 Visit 27 days ago and is expected to have used study product for 27 days since her Month 6 Visit.

QUESTION:

1.What should the site pharmacist record in rows 3 and 4 of the slip?

SCENARIO #2b: ANSWER

No TDF or placebo tablets were returned, so no product can be re-issued (can't re-issue one type of oral product without the other).

	TDF or Placebo		AND FTC/TDF or Placebo		OR 1% Tenofovir Gel or Placebo
	Total Bottles	Total Tablets	Total Bottles	Total Tablets	Total Applicators
Quantity of product actually returned *For oral participants, include empty bottles in "Total Bottles" count.*					
Quantity of unused product **not** returned *Based on participant's self-report*					
Quantity of product expected to be returned	1	03	1	03	
Quantity of product available for re-issue	0	00	0	00	

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SCENARIO #3a:

At her Month 3 Visit, a participant is dispensed the following:

- 1 bottle re-supply of TDF or placebo
- 1 bottle with 3 re-issued tablets of TDF or placebo
- 1 bottle re-supply of FTC/TDF or placebo
- 1 bottle with 3 re-issued tablets of FTC/TDF or placebo.

At her Month 4 Visit, she returns the following:

- 1 bottle containing 4 tablets of TDF or placebo (bottle was re-supplied at Month 1)
- 1 bottle containing 4 tablets of FTC/TDF or placebo (bottle was re-supplied at Month 1)

The participant states that she used all of the re-issued tablets and threw away the bottles. She says she left at her boyfriend's house 1 bottle of TDF or placebo and 1 bottle of FTC/TDF or placebo that was re-supplied at the last visit. She thinks she has 3 tablets left in each bottle.

QUESTIONS:

1.What should the site pharmacist record in rows 1 and 2 of the slip?

2.What should site staff record for items 1-4 of the form?

SCENARIO #3a: ANSWER

	TDF or Placebo		AND	FTC/TDF or Placebo		OR	1% Tenofovir Gel or Placebo
	Total Bottles	Total Tablets		Total Bottles	Total Tablets		Total Applicators
Quantity of product actually returned *For oral participants, include empty bottles in "Total Bottles" count.*	0	00		0	00		
Quantity of unused product **not** returned *Based on participant's self-report*	2	03		2	03		
Quantity of product expected to be returned							
Quantity of product available for re-issue							

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SCENARIO #3a: ANSWER

Participant ID: [ ][ ][ ] - [ ][ ][ ][ ][ ] - [ ]
Site Number — Participant Number — Chk

Product Returns

Visit Date: [ ][ ] [ ][ ][ ] [ ][ ]
dd — MMM — yy

If the participant is randomized to vaginal study product, go to item 5.

ORAL PRODUCTS RETURNED

		# bottles returned	# tablets returned
1.	Returned **TDF or placebo**:	0	00

		# bottles returned	# tablets returned
2.	Returned **FTC/TDF or placebo**:	0	00

		# bottles ***not*** returned	# tablets ***not*** returned
3.	Unused **TDF or placebo** not returned:	2	03

		# bottles ***not*** returned	# tablets ***not*** returned	
4.	Unused **FTC/TDF or placebo** not returned:	2	03	→ ***End of form.***

VAGINAL PRODUCTS RETURNED

		# applicators returned
5.	Returned **unused applicators**:	[ ][ ]

		# applicators ***not*** returned
6.	**Unused applicators** not returned:	[ ][ ]

SCENARIO #3b:

At her Month 3 Visit, a participant is dispensed the following:

- 1 bottle re-supply of TDF or placebo
- 1 bottle with 3 re-issued tablets of TDF or placebo
- 1 bottle re-supply of FTC/TDF or placebo
- 1 bottle with 3 re-issued tablets of FTC/TDF or placebo.

At her Month 4 Visit, she returns the following determined to be in good condition:

- 1 bottle containing 4 tablets of TDF or placebo (bottle was re-supplied at Month 1)
- 1 bottle containing 4 tablets of FTC/TDF or placebo (bottle was re-supplied at Month 1)

The participant states that she used all of the re-issued tablets and threw away the bottles. She says she left at her boyfriend's house 1 bottle of TDF or placebo and 1 bottle of FTC/TDF or placebo that was re-supplied at the last visit. She thinks she has 3 tablets left in each bottle.

The participant completed her Month 3 Visit 26 days ago and is expected to have used study product for 27 days since her last visit (the 27 days accounts for the fact that the participant used study product on the day of her Month 2 Visit, after she completed the visit).

QUESTION:

1.What should the site pharmacist record in rows 3 and 4 of the slip?

SCENARIO #3b: ANSWER

	TDF or Placebo		AND	FTC/TDF or Placebo		OR	1% Tenofovir Gel or Placebo
	Total Bottles	Total Tablets		Total Bottles	Total Tablets		Total Applicators
Quantity of product actually returned *For oral participants, include empty bottles in "Total Bottles" count.*							
Quantity of unused product **not** returned *Based on participant's self-report*							
Quantity of product expected to be returned	2	06		2	06		
Quantity of product available for re-issue	0	00		0	00		

SCENARIO #4a:

At her Month 7 Visit, a participant is dispensed the following:

- 1 bottle re-supply of TDF or placebo
- 1 bottle with 5 re-issued tablets of TDF or placebo
- 1 bottle re-supply of FTC/TDF or placebo
- 1 bottle with 5 re-issued tablets of FTC/TDF or placebo.

At her Month 8 Visit, she returns the following:

- 1 bottle containing 10 tablets of TDF or placebo (bottle was re-supplied at Month 7)
- 1 bottle containing 10 tablets of FTC/TDF or placebo (bottle was re-issued at Month 7).

When questioned, the participant states that she mixed the unused TDF or placebo tablets together into one bottle, and mixed the unused FTC/TDF or placebo tablets into one bottle. She says that she threw away the empty TDF or placebo and empty FTC/TDF or placebo bottles that she was re-supplied at her last visit. She states that she has brought all unused tablets with her to this visit.

QUESTIONS:

1.What should the site pharmacist record in rows 1 and 2 of the slip?

2.What should site staff record for items 1-4 of the form?

SCENARIO #4a: ANSWER

Empty bottles were not returned

	TDF or Placebo		AND FTC/TDF or Placebo		OR 1% Tenofovir Gel or Placebo
	Total Bottles	Total Tablets	Total Bottles	Total Tablets	Total Applicators
Quantity of product actually returned *For oral participants, include empty bottles in "Total Bottles" count.*	1	10	1	10	
Quantity of unused product **not** returned *Based on participant's self-report*	1	00	1	00	
Quantity of product expected to be returned					
Quantity of product available for re-issue					

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SCENARIO #4a: ANSWER

Participant ID: [ ][ ][ ] - [ ][ ][ ][ ][ ] - [ ]
Site Number — Participant Number — Chk

Product Returns

Visit Date: [ ][ ] [ ][ ][ ] [ ][ ]
dd — MMM — yy

If the participant is randomized to vaginal study product, go to item 5.

ORAL PRODUCTS RETURNED

		# bottles returned	# tablets returned
1.	Returned **TDF or placebo**:	1	10

		# bottles returned	# tablets returned
2.	Returned **FTC/TDF or placebo**:	1	10

		# bottles ***not*** returned	# tablets ***not*** returned
3.	Unused **TDF or placebo** not returned:	1	00

		# bottles ***not*** returned	# tablets ***not*** returned	
4.	Unused **FTC/TDF or placebo** not returned:	1	00 →	***End of form.***

VAGINAL PRODUCTS RETURNED

		# applicators returned
5.	Returned **unused applicators**:	[ ][ ]

		# applicators ***not*** returned
6.	**Unused applicators** not returned:	[ ][ ]

SCENARIO #4b:

At her Month 7 Visit, a participant is dispensed the following:

- 1 bottle re-supply of TDF or placebo
- 1 bottle with 5 re-issued tablets of TDF or placebo
- 1 bottle re-supply of FTC/TDF or placebo
- 1 bottle with 5 re-issued tablets of FTC/TDF or placebo.

At her Month 8 Visit, she returns the following determined to be in good condition:

- 1 bottle containing 10 tablets of TDF or placebo (bottle was re-supplied at Month 7)
- 1 bottle containing 10 tablets of FTC/TDF or placebo (bottle was re-issued at Month 7).

When questioned, the participant states that she mixed the unused TDF or placebo tablets together into one bottle, and mixed the unused FTC/TDF or placebo tablets into one bottle. She says that she threw away the empty TDF or placebo and empty FTC/TDF or placebo bottles that she was re-supplied at her last visit. She states that she has brought all unused tablets with her to this visit.

The participant completed her Month 7 Visit 25 days ago and is expected to have used study product for 25 days since her last study visit.

QUESTION:

1.What should the site pharmacist record in rows 3 and 4 of the slip?

SCENARIO #4b: ANSWER

The participant mixed re-supplied and re-issued tablets together in one bottle. Therefore, it's impossible to tell which of the tablets (if any) were re-issued at Month 7 and are now expired. To avoid the possibility of re-issuing expired tablets, "0" tablets should be recorded as available for re-issue at Month 8.

	TDF or Placebo		AND	FTC/TDF or Placebo		OR	1% Tenofovir Gel or Placebo
	Total Bottles	Total Tablets		Total Bottles	Total Tablets		Total Applicators
Quantity of product actually returned *For oral participants, include empty bottles in "Total Bottles" count.*							
Quantity of unused product **not** returned *Based on participant's self-report*							
Quantity of product expected to be returned	2	10		2	10		
Quantity of product available for re-issue	0	00		0	00		

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SCENARIO #5a:

At her Month 6 Visit, a participant is dispensed the following:

- 1 bottle re-supply of TDF or placebo
- 1 bottle with 2 re-issued tablets of TDF or placebo
- 1 bottle re-supply of FTC/TDF or placebo
- 1 bottle with 2 re-issued tablets of FTC/TDF or placebo.

A week later, she comes in for an interim visit complaining of symptoms that warrant a product hold. She left all her unused product at home. Product was held for 10 days total.

QUESTIONS:

1.Should a slip and form be completed at the interim visit?

2. If yes, what should site staff record for items 1 and 2 of the slip?

SCENARIO #5a: ANSWER

A slip and form should not be completed at the interim visit, since product was not returned, re-supplied, or re-issued.

SCENARIO #5b:

At her Month 6 Visit, a participant is dispensed the following:

- 1 bottle re-supply of TDF or placebo
- 1 bottle with 2 re-issued tablets of TDF or placebo
- 1 bottle re-supply of FTC/TDF or placebo
- 1 bottle with 2 re-issued tablets of FTC/TDF or placebo.

A week later, she comes in for an interim visit complaining of symptoms which warrant a product hold. She left all her unused product at home. Product was held for 10 days total.

The same participant returns 10 days later, and completes a second interim visit to resume product use. She returns the following:

- 1 bottle containing 25 tablets of TDF or placebo (bottle was re-supplied at Month 6)
- 1 bottle containing 25 tablets of FTC/TDF or placebo (bottle was re-supplied at Month 6)
- 1 empty bottle of TDF or placebo (re-issued at Month 6)
- 1 empty bottle of FTC/TDF or placebo (re-issued at Month 6).

She states that she left the tablets in her hot car all week, and noticed that they were soft and chalky. The site pharmacist decides to advise the participant not to use this product. The pharmacist discusses this with the site clinician (authorized prescriber), who requests a product re-supply. Based on this request, the site pharmacist re-supplies the participant with 1 bottle of TDF or placebo and 1 bottle of FTC/TDF or placebo.

QUESTIONS:

1.What should the site pharmacist record in rows 1-4 of the slip?

2.What should site staff record for items 1-4 of the form?

SCENARIO #5b: ANSWER

	TDF or Placebo		AND	FTC/TDF or Placebo		OR	1% Tenofovir Gel or Placebo
	Total Bottles	Total Tablets		Total Bottles	Total Tablets		Total Applicators
Quantity of product actually returned *For oral participants, include empty bottles in "Total Bottles" count.*	2	25		2	25		
Quantity of unused product **not** returned *Based on participant's self-report*	0	00		0	00		
Quantity of product expected to be returned	2	25		2	25		
Quantity of product available for re-issue	0	00		0	00		

SCENARIO #5b: ANSWER

Participant ID: ☐☐☐ - ☐☐☐☐☐ - ☐ (Site Number - Participant Number - Chk)

Product Returns

Visit Date: ☐☐ (dd) ☐☐☐ (MMM) ☐☐ (yy)

If the participant is randomized to vaginal study product, go to item 5.

ORAL PRODUCTS RETURNED

		# bottles returned	# tablets returned
1.	Returned **TDF or placebo**:	2	25

		# bottles returned	# tablets returned
2.	Returned **FTC/TDF or placebo**:	2	25

		# bottles ***not*** returned	# tablets ***not*** returned
3.	Unused **TDF or placebo** not returned:	0	00

		# bottles ***not*** returned	# tablets ***not*** returned	
4.	Unused **FTC/TDF or placebo** not returned:	0	00	→ ***End of form.***

VAGINAL PRODUCTS RETURNED

		# applicators returned
5.	Returned **unused applicators**:	☐☐

		# applicators ***not*** returned
6.	**Unused applicators** not returned:	☐☐

SCENARIO #5c:

At her Month 7 Visit, the same participant returns the following determined to be in good condition:

- 1 bottle containing 16 tablets of TDF or placebo (re-supplied at second interim visit)
- 1 bottle containing 16 tablets of FTC/TDF or placebo (re-supplied at second interim visit).

She has no unused study product left at home or in her possession. She completed her second interim visit 14 days ago and was expected to have used study product for 14 days since the second interim visit. Her Month 6 Visit was 31 days ago.

QUESTIONS:

1. What should the site pharmacist record in rows 1-4 of the slip?

2. What should site staff record for items 1-4 of the form?

SCENARIO #5c: ANSWER

	TDF or Placebo		AND	FTC/TDF or Placebo		OR	1% Tenofovir Gel or Placebo
	Total Bottles	Total Tablets		Total Bottles	Total Tablets		Total Applicators
Quantity of product actually returned *For oral participants, include empty bottles in "Total Bottles" count.*	1	16		1	16		
Quantity of unused product **not** returned *Based on participant's self-report*	0	00		0	00		
Quantity of product expected to be returned	1	16		1	16		
Quantity of product available for re-issue	1	16		1	16		

SCENARIO #5c: ANSWER

Participant ID

[ ][ ][ ] - [ ][ ][ ][ ][ ] - [ ]

Site Number | Participant Number | Chk

Product Returns

Visit Date

[ ][ ] [ ][ ][ ] [ ][ ]

dd *MMM* *yy*

If the participant is randomized to vaginal study product, go to item 5.

ORAL PRODUCTS RETURNED

		# bottles returned	*# tablets returned*
1.	Returned **TDF or placebo**:	1	16
2.	Returned **FTC/TDF or placebo**:	1	16
3.	Unused **TDF or placebo** not returned:	0	00
4.	Unused **FTC/TDF or placebo** not returned:	0	00 → ***End of form.***

		*# bottles **not** returned*	*# tablets **not** returned*
3.	Unused **TDF or placebo** not returned:	0	00
4.	Unused **FTC/TDF or placebo** not returned:	0	00 → ***End of form.***

VAGINAL PRODUCTS RETURNED

		# applicators returned
5.	Returned **unused applicators**:	[ ][ ]

		*# applicators **not** returned*
6.	**Unused applicators** not returned:	[ ][ ]

Questions?

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